Supreme Court, U.S.
FILED

No 03 1228 DEC 16 2003

OFFICE OF THE CLERK

In The Supreme Court of the United States

BALDEV RAJ BHUTANI and ALRA LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

◆

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

◆

PETITION FOR WRIT OF CERTIORARI

◆

Baldev Raj Bhutani
Pro Se
Federal Prison Camp
P.O. Box 1000
Duluth, Minnesota 55814

Petitioner

THE LEX GROUP^DC ♦ One Massachusetts Ave., NW ♦ Suite 670 ♦ Washington, DC 20001
(202) 789-2400 ♦ Fax: (202) 789-1911 ♦ www.thelexgroupdc.com

I. QUESTIONS PRESENTED

1. Whether Appellant/Petitioner's rights to an appeal, heard on merits as a matter of law, are violated since constitutional issues presented for full consideration were substantial and properly raised, but never ruled on their merits by the Seventh Circuit Court of Appeals, arising from changed circumstances and new law established by U.S. v. Neder, 527 U.S. 1 (1999) and U.S. v. Gaudin, 515 U.S. 506 132 L.Ed. 2d. 444, 115 S.Ct. 2310 (1995) and accepted by Department of Justice (DOJ) in 2002 that Neder decision applies to felony provision of FD&C Act as DOJ did not file for Certiorari in U.S. v. Watkins, 278 F.3d. 961 (9th Cir. 2002).

2. Whether Seventh Circuit Court of Appeals properly dismissed 28 U.S.C. § 2255 petition filed Pro Se from a prison inmate under 28 U.S.C.S. § 1915(a)(3) and contrary to Supreme Court decision in Neitzke v. Williams, 490 U.S. 319, 104 L.Ed. 2d. 338 (1989) and refused to issue a Certificate of Appealability.

3. Whether District Court and Court of Appeals for the Seventh Circuit can, when convenient, selectively refuse to apply law established by Supreme Court of the United States, as it did in this case while Appellant/Petitioner serves time in a Federal Prison.

II. PARTIES TO THE PROCEEDINGS

Appellant/Petitioner BALDEV RAJ BHUTANI, Ph. D. and ALRA LABORATORIES, INC. respectfully petition for a Writ of Certiorari to review the denial of a Certificate of Appealability by United States Court of Appeals for the Seventh Circuit.

ALRA LABORATORIES, INC. located in Gurnee Illinois does not have any parent companies or subsidiaries.

III. TABLE OF CONTENTS

Page

I. QUESTIONS PRESENTED i

II. PARTIES TO THE PROCEEDINGS ii

III. TABLE OF CONTENTS iii

IV. TABLE OF AUTHORITIES vi

V. OPINIONS BELOW 1

VI. JURISDICTION 2

VII. CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED IN THE CASE 3

VIII. STATEMENT OF THE CASE 4

  1. BACKGROUND ON COUNTS OF CONVICTION 4

  2. BACKGROUND ON APPEAL, APPEAL NO. 03-1120 BEFORE THE COURT OF APPEALS FOR THE SEVENTH CIRCUIT 6

  3. BACKGROUND ON PRIOR OPINIONS BY THE SEVENTH CIRCUIT COURT OF APPEALS IN UNITED STATES V. BHUTANI AND DISTRICT COURT IN 1997 WL 811689. 8

4. THE DISTRICT COURT DENIED DEFENDANTS' RENEWED NEW TRIAL MOTION ON REMAND IN YEAR 1999 ON PROCEDURAL GROUNDS. 11

5. AFTER FAILING TO OFFER AN OPINION ON JURY INSTRUCTIONS ON MATERIALITY, THE COURT OF APPEALS SUBSTITUTED ITS OWN JUDGEMENT ON MATERIALITY OF FDA ACT. 13

6. THE CHANGED CIRCUMSTANCES AND NEW LAW ACCEPTED BY THE DEPARTMENT OF JUSTICE WHICH LED TO DEFENDANT'S 28 U.S.C. § 2255 MOTION. 16

IX. REASONS FOR GRANTING THE WRIT 18

X. ARGUMENT 18

1. PRO SE PLEADINGS ARE HELD TO LESS STRINGENT STANDARDS THAN FORMAL PLEADINGS DRAFTED BY LAWYERS. 18

2. APPELLANT/PETITIONER'S RIGHTS TO APPEAL TO BE HEARD ON MERITS, AS A MATTER OF LAW, ARE VIOLATED IF THE COURT OF APPEALS DID NOT RULE ON ISSUES OF JURY INSTRUCTIONS ON MATERIALITY AS RAISED ON DIRECT APPEAL AND IN 28 U.S.C. § 2255 PETITION. 20

3. APPELLANT/PETITIONERS 28 U.S.C. § 2255 PETITION IS PROPERLY FILED AND IT RAISED SUBSTANTIAL CONSTITUTIONAL ISSUES RESULTING FROM CHANGED CIRCUMSTANCES AND SUPREME COURT LAW 21

4. REFUSAL TO ISSUE A CERTIFICATE OF APPEALABILITY IS CONTRARY TO LAW AS ESTABLISHED BY THIS COURT AND THE COURT OF APPEALS FOR THE SEVENTH CIRCUIT 28

XI. CONCLUSION 29

APPENDIX

IV. TABLE OF AUTHORITIES

Page(s)

Cases:

Bennett v. United States,
119 F.3d 470 (7th Cir. 1997) 22

Brady v. Maryland,
373 U.S. 83, 83 S. Ct. 1194 (1963) 1, 21

Conley v. Gibson,
355 U.S. 41 (1957), 2 L. Ed. 80,
78 S. Ct. 99 (1957) 19

Felker v. Turpin,
518 U.S. 651, 116 S. Ct. 2333,
135 L. Ed. 2d. 827 (1996) 22

Fleming v. Florida Citrus Exchange,
358 U.S. 153, 79 S. Ct. 160 26

Garrett v. United States,
178 F.3d 940 (7th Cir. 1999) 22

Griffin v. Kentucky,
470 U.S. 314 (1987) 23, 25

Haines v. Kerner,
404 U.S. 519, 30 L. Ed. 2d. 652,
92 S. Ct. 594 (1972) 18

Hohn v. United States,
524 U.S. 236, 141 L. Ed. 2d. 242,
118 S. Ct. 1969 (1998) 2

Neitzke v. Williams,
490 U.S. 319, 104 L. Ed. 2d 338 (1989) i

O'Connor v. United States,
133 F.3d 548 (7th Cir. 1998) 22

Pate v. Stevens,
163 F.3d 437 (7th Cir. 1998) 19

Sullivan v. Louisiana,
508 U.S. 275, 124 L. Ed. 2d. 182,
113 S. Ct. 2078 (1993) .... passim

Townsend v. Sain,
372 U.S. 293, 83 S. Ct. 745,
9 L. Ed. 2d. 770 (1963) 7, 18, 19, 28

United States v. Baumgardner,
85 F.3d 1305 (8th Cir. 1996) 25

United States v. Bhutani,
175 F.3d 572 (7th Cir. 1999) .... passim

United States v. Bhutani,
266 F.3d 661 (7th Cir. 2001) .... passim

United States v. Gaudin,
515 U.S. 506, 132 L. Ed. 2d. 444,
115 S. Ct. 2310 (1995) .... i, 3, 23, 24

United States v. Jones,
21 F.3d 165 (7th Cir. 1994) 25

United States v. Lexington Mills & Elevator Co,
232 U.S. 399, 34 S. Ct. 337 26

United States v. Mohrbacher,
182 F.3d 1042 (9th Cir. 1999) 26

United States v. Mazak,
789 F.2d 580 (7th Cir. 1986) 28

United States v. Nechy,
827 F.2d 1161 (7th Cir. 1987) 19, 21

United States v. Neder,
527 U.S. 1 (1999) .... passim

United States v. Orlano,
507 U.S. 725, 113 S. Ct. 1770,
123 L. Ed. 2d. 508 (1993) 24

United States v. Watkins,
278 F.3d 961 (9th Cir. 2002) .... passim

Walker v. O'Brien,
216 F.3d 629 (7th Cir. 2000) 19

Williams v. Parke,
133 F.3d 971 (7th Cir. 1997) 19

Constitutional Provisions:

U.S. CONST. amend. V 3, 23, 24, 28

U.S. CONST. amend. VI 3, 23, 24, 28

Statutes:

21 U.S.C. §§ 301 et seq
(Food, Drug, and Cosmetic Act) .... passim

21 U.S.C. § 333(a)(2) 4

21 U.S.C. § 331(e) 4

21 U.S.C. § 355(j) 4

28 U.S.C. § 1254(1) 2

28 U.S.C. § 1915(a)(3) .... i, 2

28 U.S.C. § 2253 2

28 U.S.C. § 2253(c)(2) 19

28 U.S.C. § 2255 .... passim

Regulations:

21 C.F.R. § 210 ....8, 9

21 C.F.R. § 211 ....8, 9

Guidelines:

U.S.S.G. § 2F1.1 4

U.S.S.G. § 2N2.1 4

U.S.S.G. § 2N2.1(b) 29

U.S.S.G. § 2N2.1(b)(1) 4, 29

Rules:

Supreme Court Rule 10(a) 3

Supreme Court Rule 10(c) 3

Supreme Court Rule 13.. 3

Other Authority:

4 W. Blackstone,
Commentaries on the Laws of England (1769)........................ 23

V. OPINIONS BELOW

On December 16, 1997, district judge John F. Grady entered a 30-page Memorandum Opinion granting Defendants a new trial based on newly discovered evidence and/or violations of Brady v. Maryland, App. H. The Seventh Circuit issued an opinion reversing the district court and remanding for reinstatement of convictions and sentencing, reported at 175 F.3d 572. App. F. This Court denied Certiorari. 528 U.S. 1161 (February 22, 2000), App. G.

On remand, the district court denied Defendants' renewed motion for a new trial, holding that materiality was not an element of an "intent to defraud and mislead" under the Food, Drug, & Cosmetic Act ("FD&C Act"), and noting that although the government had changed its position during appeal, the Seventh Circuit's first opinion held otherwise.

During sentencing hearings, the district court found that counts of conviction did not cause the drugs to be unsafe or ineffective. Tr. 1/24/00 at 39-41 and the appellate court agreed with this finding, De Novo. The district court also found that the government had not proved that Defendants' conduct continued past November 1, 1991. Tr. 6/16/00 at 82, App. L. It sentenced Defendant Bhutani to 30 months imprisonment, a fine and restitution.

The Seventh Circuit affirmed Defendants' conviction and sentence in an opinion reported at 266 F.3d 661, App. D.

On June 17, 2002, this court denied, without comment or opinion defendants Certiorari Petition App. E and defendant Bhutani voluntarily surrendered to Federal Prison Camp on August 26, 2002.

On March 8, 2002 Defendant/Appellant filed Pro Se, his present 28 U.S.C. § 2255 (Petition for Writ of Habeas Corpus) citing Constitutional rights and changed circumstances and law. On November 21, 2002, District Court denied this petition without hearing, App. C.

Defendant/Appellant filed for a Certificate of Appealability. District Court and Court of Appeals for the Seventh Circuit denied Certificate of Appealability on September 24, 2003, App. A.

VI. JURISDICTION

Petitioner/Appellant Baldev R. Bhutani (BHUTANI) is before this court on a dismissal of a 28 U.S.C. § 2255 Motion to vacate his conviction and sentence, based on changed circumstances and new law established by the Supreme Court of the United States.

The court's jurisdiction arises from 28 U.S.C. § 1254(1) to review denial of application for Certificate of Appealability (COA) by a Circuit judge or a panel of a Court of Appeals. Please see Hohn v. United States, 524 U.S. 236, 141 L. Ed. 2d. 242, 118 S. Ct. 1969 (1998).

District Court Judge Honorable John Grady, Northern District of Illinois issued an order on November 21, 2002 and denied a Certificate of Appealability pursuant to 28 U.S.C. § 2253 on December 5, 2002.

Petitioner/Appellant filed for an appeal and Certificate of Appealability under 28 U.S.C. § 2253 and 28 U.S.C. § 1915(a)(3). A panel of Court of Appeals for the Seventh Circuit denied a COA on September 24, 2003.

Appellant/Petitioner now submits a Petition for Writ of Certiorari pursuant to Rules 10(a) and 10(c) from Appellate Court's final order of denial of COA.

Futhermore, Appellant/Petitioner submits that this Writ for Certiorari has been properly commenced within the statutory time period as set forth by Rule 13 of the Rules of the Supreme Court of the United States.

VII. CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED IN THE CASE

The Fifth Amendment to the United States Constitution guarantees that no one will be deprived of liberty without "due process of law" and the sixth, that in all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial by an impartial jury. The Supreme Court has held that these provisions require criminal convictions to rest upon a jury determination that the defendant is guilty of every element of the crime with which he is charged, beyond a reasonable doubt. Sullivan v. Louisiana, 508 U.S. 275, 124 L. Ed. 2d. 182, 113 S. Ct. 2078 (1993).

In U.S. v. Gaudin, 515 U.S. 506, 132 L. Ed. 2d. 444 115 S. Ct. 2310, Supreme Court held that trial judges refusal to allow the jury to determine the materiality......... infringed the accused's right guaranteed by the Fifth Amendment's due process clause and the Sixth Amendment's right to a jury trial..... where government conceded that materiality was an element of the offense.

In U.S. v. Neder, 527 U.S. 1(1999) Supreme Court held that when Congress of the United States used the term "to defraud" in the mail and wire fraud statutes, Congress necessarily incorporated the Common Law requirement of materiality as an element of the offense. In Neder this court held that common law could not have conceived of "fraud" without materiality, 527 U.S. at 22. In U.S. v. Watkins, 278 F.3d 961 (9th Cir. 2002) the panel found that Neder decision applies to violations in FD&C Act. Department of Justice (DOJ) did not file for a Writ to the Watkins decision.

Between 1984 and 1990, 21 U.S.C. 331(e) listed prohibited acts under the Federal Food, Drug and Cosmetic Act, including violations of 21 U.S.C. 355(j). 21 U.S.C. 333(a)(2) provides, in relevant part, "if any person.... commits such a violation (of 21 U.S.C. 331) with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined...." U.S.S.G. 2N2.1 applies to "Violations of Statutes and Regulations Dealing With Any.... Drug," Application Note 1 provides, "This guideline assumes a regulatory offense that involved knowing or reckless conduct." 2N2.1 section (b)(1), effective November 1, 1992, provides "[i]f the offense involved fraud, apply 2F1.1 (Fraud and Deceit)." U.S.S.G. 2F1.1 provides sentencing enhancements for fraud "loss."

VIII. STATEMENT OF THE CASE

1. BACKGROUND ON COUNTS OF CONVICTION

On February 15, 2000, Mr. Bhutani was sentenced to a 30 month prison term on his convictions for food and drug regulatory offenses in Counts 1, 3, 4, 6, 7, 8, and 10. On appeal, on September 12, 2001, a panel of the Seventh Circuit affirmed Dr. Bhutani's convictions and sentence on the regulatory offense counts.

Pursuant to Mr. Bhutani's request and over the Government's objections Appellate Judge, Honorable William J. Bauer, granted his motion to stay issuance of mandate pending disposition of petition for Writ of Certiorari.

The counts of conviction related to three separate episodes at ALRA's generic drug manufacturing plant. First, part of Count One (a conspiracy count) and Counts Three, Four, and Six alleged that, in August 1998, ALRA employees added sodium hydroxide to decomposed Lactulose Syrup to mask degradation of the drug product.

Second, the conspiracy count and Counts Seven and Eight alleged that in September 1989, ALRA manufactured different lots of Lactulose Syrup using raw material, Lactulose Concentrate, that has arrived in leaking drums, allegedly exposing the raw material to a "possibility" of contamination.

Third, the conspiracy count and Count Ten alleged that in 1989, a stainless steel pipe accidentally fell into a mill during ALRA's manufacture of a different generic drug product, K+10 (potassium chloride), causing the lot to be contaminated with metal shavings.

On February 12, 2002, Mr. Bhutani filed his Certiorari Petition with the Supreme Court seeking to overturn his convictions and sentence. Mr. Bhutani claimed, as he had before District Court and the Seventh Circuit, inter alia, that the Government was required to prove beyond a reasonable doubt that Mr. Bhutani's regulatory offenses were material as set forth in Neder. The Government told the Supreme Court that it should deny Dr. Bhutani's Certiorari Petition because, inter alia, **"[t]he [Seventh Circuit] court of appeals did not address whether Neder requires a materiality finding for convictions under the [Food, Drug, and Cosmetic Act]." (emphasis added). To the Supreme Court of the United States, the Government admitted that the 7th Circuit did not rule on Defendants' appeal on the merits.**

Surprised by the Governments acceptance of the ninth circuit decision in United States v. Watkins, 278 F.3d

961 and Governments complete reversal on United States v. Bhutani, 266 F.3d 661 before the Supreme Court, on March 8, 2002 Mr. Bhutani filed a Habeas Corpus petition or regulatory offenses in cause number 02 C 1817 before District Court Judge, Honorable John Grady.

2. BACKGROUND ON APPEAL, APPEAL NO. 03-1120 BEFORE THE COURT OF APPEALS FOR THE SEVENTH CIRCUIT

March 8, 2002, Appellant/Petitioner Bhutani filed a motion to vacate, set aside or correct sentence pursuant to 28 U.S.C. § 2255 ("Petition for Writ of Habeas Corpus") before the District Court Judge that his constitutional rights to a fair trial were violated. Dr. Bhutani cited U.S. v. Watkins, 278 F.3d 961 (9th Circuit 2002). Appellant/Petitioner claimed that in light of these two parallel cases directly on point to, the law on felony violations involving Food, Drug, and Cosmetic Act (FDCA) was now fully developed and United States Department of Justice had accepted this as Law as the Government did not appeal this adverse decision in Watkins to the Government to En Banc Court of the Ninth Circuit or to the United States Supreme Court.

Appellant, Petitioner also cited the Government's admission to the Supreme Court that "[t]he [Seventh Circuit] Court of Appeals did not address whether Neder v. United States, 527 U.S. 1(1999) requires a materiality finding for convictions under the [Food, Drug, and Cosmetic Act]". Therefore, the Government admitted that the 7th Circuit did not rule on Defendants' claim on the merits (emphasis added). These facts clearly established changed Circumstances of Law.

Questions Presented By Appellants Appeal Were:

i. Whether the District Court erred when it stated that "the Court of Appeals has ruled on each of the matters and we are bound by the rulings" as even the Government conceded to the Supreme Court of the United States that the Court of Appeals for the Seventh Circuit did not rule on law established by U.S. v. Neder, 527 U.S. 1(1999).

ii. Whether the District Court erred when it failed to grant evidentiary hearings on Defendants' 28 U.S.C. § 2255 petition (02 C 1817) and failed to make findings of fact on Petitioner's claims that Prosecutors made false and misleading statements to the Supreme Court of the United States, (and other Courts in the Seventh Circuit) as claim alleged statements that went beyond the Government's statements in response to "Brady Violations" on Counts 3, 4, and 6 on which the 7th Circuit reversed in 1999. Townsend v. Sain, 372, U.S. 293, 312-13, 83 S. Ct. 745, 756-57, 9 L. Ed. 2d. 770 (1963).

iii. Whether the District Court erred when it refused to review Defendant, Petitioner's sentence claims in light of changed circumstances and law as developed by U.S. v. Watkins, 278 F.Ed. 961 (9th Cir. 2002) and U.S. v. Neder, 527 U.S. 1(1999) as even the 7th Circuit concluded that there was no evidence that consumers received unsafe or ineffective drugs.

3. BACKGROUND ON PRIOR OPINIONS BY THE SEVENTH CIRCUIT COURT OF APPEALS IN UNITED STATES V. BHUTANI AND DISTRICT COURT IN 1997 WL 811689.

The Court of Appeals for the Seventh Circuit has issued two opinions:

- United States v. Bhutani, 175 F.3d 572
  (7th Cir. 1999)
  Appeal No. 98-1154;

- United States v. Bhutani, 266 F.3d 661
  (7th Cir. 2001)
  Appeal No. 00-1523 and 00-2679.

If we were to carefully review two appellate decisions, we will find that the following facts have evolved.

A. Issue of criminal law relating to affirmative duty of the FDA and DOJ to disclose exculpatory evidence on issue of guilt or punishment. U.S. v. Bhutani, 175 F.3d 572, 573, 577

B. Government's affirmative statements that it never argued and did not challenge the safety or efficacy of the drugs, ...it only argued that drugs did not meet FDA regulations, 21 CFR 210 and 211. U.S. v. Bhutani, 175 F.3d 578 and U.S. v. Bhutani, 266 F.3d 661

C. Loss to consumers based on gain from consumers receiving mislabeled drugs was not an issue as defendants were found not guilty on Counts 2 and 5 of the indictment where mislabeling was alleged. U.S. v. Bhutani, 266 F.3d 664

D. No one testified to any harm resulting from drug batches and testimony at trial revealed drugs were not unsafe or ineffective.

E. Loss to consumers was based on gain on consumers receiving drugs that were not manufactured according to FDA regulations and not because the drugs were not safe or effective. U.S. v. Bhutani, 266 F.3d 669

F. Jury Instructions: Appellants and the Government agree that Jury received no instructions on:

a. How defendants violated FDA regulations as specified in 21 CFR 210 and 211 on CGMP and/or

b. If these violations were material if District Court and Appellate Courts agree that they did not effect the safety or efficacy of the drugs?

In spite of defendants objections, both in Judge Grady's chambers and on record, jury was given no instructions on how defendants violated FDA regulations and if those sections that violated regulations were material to a felony conviction. Tr. 5863, 5866-77 App I.

G. The District Court granted a new trial in an unpublished opinion in 1997 WL 811689, App H.

After trial that ended in February 1996, a publication of the United States Pharmacopoeia suggested in June 1996 that FDA has been in possession of data showing that there was no correlation between a decline in the pH of Lactulose and its medical effectiveness. The district court ordered post-trial discovery over the government's objection. In a 30-page Memorandum Opinion that quoted extensively from the government's arguments to the jury and its questions to expert witnesses, the district court found that Lactolose stability data in FDA's files contradicted the government's theory that Defendants had added sodium hydroxide to Lactulose lots to raise their pH and thus conceal their "degradation". Explicitly finding that the stability data in FDA's filed "seriously undermines the court's confidence in the verdicts," the district court granted Defendant's motion for a new trial, App H. (an unpublished opinion 1997 WL 811689)

H. The Seventh Circuit in their opinions adopted the Government's representations.

The government claimed that at trial it "did not dispute that before being spiked with sodium hydroxide [lots 52-230 and 52-231] were within the pH range, medically effective, and stable." The Seventh Circuit reversed, adopting the government's representations that "the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578

I. During sentencing hearings in June 2000, Honorable Judge Grady also held that there were substantial issues of law or fact likely to result in an order for a new trial and it also said that "If the defendants do get the attention of the Court of Appeals, there is good likelihood that a new trial will result...." Tr. 2/15/00 at 121-22.

In its unpublished opinion reported as 1997 WL 811869 District Court Judge Honorable Judge Grady found that testimony was balanced and verdict could have gone either way. During trial District Court denied Defendants request for a jury instruction that materiality was an element of fraud in FD&C Act. Tr. 5863, 5866-77.

4. THE DISTRICT COURT DENIED DEFENDANTS' RENEWED NEW TRIAL MOTION ON REMAND IN YEAR 1999 ON PROCEDURAL GROUNDS.

After remand the district court rejected Defendants' motion for a new trial based on its failure to give jury instructions that materiality was an element of felony violations under the FD&C Act. The district court held, "We agree with the government that [United States v.] Neder's materiality requirement does not apply to the statutes involved in this case."

During sentencing in January - June 2000, district court found that the government had failed to prove, during trial or sentencing, that the offenses of conviction had rendered ALRA's drugs unsafe or ineffective:

> Taking the counts one by one, there is no evidence that Dr. Bhutani regarded the injection of Lactulose into the individual bottles with syringes as creating a risk of serious bodily harm to people who might use the Lactulose Syrup. What was being injected was sodium hydroxide, which was something that was normally added to the drug. What occurred here was that it was added in a different manner than authorized by regulations, and the addition in that manner was not documented....

The government had itself changed its position as to what the risk was at least three times during the course of this litigation. It told the jury at trial that the risk was in the Lactulose itself in that it had degraded or decomposed to the point where it was not longer medically effective and that the injections of the sodium hydroxide were made to mask or conceal that fact....

When the case went up on appeal, the government took a different position....

[As to counts Seven and Eight] There is no evidence whatsoever that the Lactulose that was used from the leaking drums had anything medically dangerous bout it or that it would cause anybody any injury. There was no evidence of any actual contamination. The jury found the defendants guilty on the proposition that the reasonable possibility of contamination and the risk of serious physical injury are two different things.

People eat contaminated food every day of their lives. There is nobody in this room who won't eat some before the day is out. Our bodies are amazingly capable of warding off ill effects from contamination. And there is no evidence at all in this record that anything about these leaking drums was in fact dangerous to anybody....

Now we come to the K+10 tablets. There is no evidence that anyone was likely to be hurt from these tiny metal fragments that were in some of the pills. As the government

> concedes, we don't know how small the fragments were. They were certainly tiny. And there is no evidence that they presented a risk of serious, and I [underscore] the word "serious" bodily injury, or that Dr. Bhutani was conscious of such a serious risk.

Tr. 1/24/00 at 39-41. App J.

At the same hearing District Court Judge John Grady found that conspiracy proved at trial was limited to the overt acts same as in the counts of conviction.

5. AFTER FAILING TO OFFER AN OPINION ON JURY INSTRUCTIONS ON MATERIALITY, THE COURT OF APPEALS SUBSTITUTED ITS OWN JUDGEMENT ON MATERIALITY OF FDA ACT.

There was a major disagreement between the Defendants and the Government on the theory of alleged crimes. The government portrayed the defendants as profit-hungry monsters who were willing to put the public's safety at risk in order to make a buck by putting ineffective drugs on the market.

The appellate court reviewed the trial testimony and declared:

> "After reviewing the trial transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit or close to unfit."

United States v. Bhutani, 175 F.3d 578

> "Neither Dr. Hicks nor any other government witness, ever testified that the Lactulose in question was ineffective."
>
> United States v. Bhutani, 175 F.3d 578

The appellate court in a second opinion said the following:

> "A second read of the trial transcript reveals that the government's position at trial and on appeal has been consistent. The government did not show at trial that the Lactulose was outside accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected. The medical efficacy of the Lactulose was only mentioned by the government to explain the significance of expiration dating to the jury."
>
> United States v. Bhutani, 266 F.3d 664

The panel's opinion did not even address Defendants' arguments that the district court should have instructed the jury that materiality was an element of an "intent to defraud and mislead" under the FD&C Act, that the district court should have specified to the jury how Defendants allegedly violated the FD&C Act or FDA regulations.

Loss to consumer was justified by the sentencing judge as follows:

> "I find that there was an issue as to whether these drugs had been properly manufactured.
>
> I'm not saying that there was an issue as to whether they would be injurious to health or necessarily even an issue as to whether they would be effective for their pharmaceutical purpose. What I find, rather, is that there was an issue as to whether they had been manufactured in such a way that the consumers of those drugs were being sold something other than what they thought they were buying.
>
> I don't think that any consumer of any of those drugs would have bought those drugs had the consumer known what had happened to them."
>
> "Here consumers bargained for FDA-approved drugs that were in compliance with the law. This they did not get."
>
> Tr. 2/15/00 at App K.

The appellate court held that while they do not agree with District Judge's reasoning, the court will however adopt the loss value because:

> "The medical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry; rather, the district court was justified in determining that there was a loss because consumers did not get

> what they bargained for. We agree with the district court's decision that there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law."
>
> United States v. Bhutani, 266 F.3d 669

6. THE CHANGED CIRCUMSTANCES AND NEW LAW ACCEPTED BY THE DEPARTMENT OF JUSTICE WHICH LED TO DEFENDANT'S 28 U.S.C. § 2255 MOTION.

It is now undisputed and accepted by the Department of Justice that United States Supreme Court's decision in United States v. Neder applies to the felony provisions of the FD&C Act.

In United States v. Neder, 527 U.S. 1(1999), Supreme Court held that when Congress used the term "to defraud" in the mail and wire fraud statutes, Congress necessarily incorporated the common law requirement of materiality as an element of the offense. Indeed, Supreme Court held that the "common law could not have conceived of 'fraud' without materiality". 527 U.S. at 22. Every offense of conviction in this case alleged an "intent to defraud or mislead". Congress used the same common law term "to defraud" in the Food, Drug, & Cosmetic Act (FD&C Act) that is used in the mail and wire fraud statutes. Neder was thus directly on point, and required the jury to find an element of materiality in FD&C Act offenses.

On January 29, 2002, the Court in United States v. Watkins, 278 F.3d 961 (9th Cir. 2002), reversed the defendant's felony conviction on FDCA Counts because [t]he Government did not prove that the defendant's misstatements were material misrepresentations as required by Neder. The Government did not appeal this adverse decision to En Banc Court of the Ninth Circuit or to the United States Supreme Court (Emphasis added).

The Ninth Circuits decision carefully analyzed the impact of U.S. v. Neder on felony provisions of the FD&C Act.

The Ninth Circuit separately analyzed "intent.... to mislead" under the FD&C Act. Looking to the plain meaning of that phrase, the Ninth Circuit held that an "intent to mislead" also requires materiality.

It is significant to note that both District Court and Court of Appeals for the Seventh Circuit opined that violations were not material as they did not impact drug's efficacy or safety, but refuse to address the issue that if jury was given proper instructions on materiality, the jury will have found defendant's not guilty.

The materiality issue in this case is particularly important because of the broad regulatory sweep on the FD&C Act, and because of the government's theory of conviction in this case.

The criminalizing of all violations of FDA regulations to the level of felony convictions, no matter how immaterial to efficacy or safety of drugs violates Neder's reasoning, and also is a dangerous, and potentially limitless abuse of the prosecution's discretion to expose selected pharmaceutical executives to felony sentences under the FD&C Act as is the case here.

IX. REASONS FOR GRANTING THE WRIT

Appellant/Petitioner's 28 U.S.C. § 2255 petition was properly filed and raised substantial Constitutional issues resulting from changed circumstances and this courts opinions. District Courts refusal to consider merits of the issues raised and reject the petition on prosedural grounds violated Appellant/Petitioner's rights to petition be heard consistent with laws established by this court and the Court of Appeals for the Seventh Circuit.

Refusal to issue a Certificate of Appealability is contrary to opinion in Townsend v. Sain, 372, U.S. 293, 312-13, 83 S. Ct. 745, 756-57, 9 L. Ed. 2d. 770 (1963).

The District Court's refusal to instruct the jury that materiality was an element of "intent to defraud and mislead" under the FD&C Act conflicts with decision of this court in United States v. Neder, 527 U.S. 1(1999). After the Seventh Circuit ignored this important issue on direct appeal, the Ninth Circuit held in 2002 that materiality was an element of felony violations under the FD&C Act.

X. ARGUMENT

1. PRO SE PLEADINGS ARE HELD TO LESS STRINGENT STANDARDS THAN FORMAL PLEADINGS DRAFTED BY LAWYERS.

The United States Supreme Court holds allegations of a pro se complaint to less stringent standards than formal pleadings drafted by lawyers. Haines v. Kerner, 404 U.S. 519, 30 L. Ed. 2d. 652, 92 S. Ct. 594. This court, in a per curiam opinion, expressing the unanimous view of this court, held that petitioner was entitled to an opportunity to offer proof Id. The court opined that "....we can not say with assurances that under the allegations of the pro se complaint, which we hold to less stringent standards than formal pleadings drafted by lawyers, it appears beyond doubt that the support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957), 2 L. Ed. 80, 84, 78 S. Ct. 99

In this case, petitioner asked the court to accept his appeal and grant a Certificate of Appealability (COA) under either of the two conditions, ie "a substantial showing of denial of a Constitutional rights". See 28 U.S.C. § 2253(c)(2); Williams v. Parke, 133 F.3d 971, 975 (7th Circuit 1997) or "an appeal filed in good faith" where a court need only find that a reasonable person could suppose that the appeal has some merit. Please see Walker v. O'Brien,216 F.3d 629 (7th Circuit 2000); Pate v. Stevens, 163 F.3d 437, 439 (7th Circuit 1998).

In Townsend v. Sain, 372 U.S. 293 (1963), this court held that an issue previously raised on direct appeal can not be relitigated in §2255 petition; only if the issue was resolved on merits (emphasis added). The appellate court side stepped all legal standards established by this court and denied relief without a written opinion accepting District Court's denial on procedural grounds under United States v. Nachy, 827 F.2d 1161, 1164 (7th Circuit 1987).

During sentencing the same District Court Judge found that if the appellate court reviewed the merits of case, a reversal will occur. Appellate Court's refusal to even rule on issues relating to the jury instructions on materiality as required by Neder v. United States, 527 U.S. 1(1999) is quite telling as even the prosecuting attorney conceded to this court that the Court of Appeals for the Seventh Circuit did not rule on the Neder issues by the petitioner/appellant.

2. APPELLANT/PETITIONER'S RIGHTS TO APPEAL TO BE HEARD ON MERITS, AS A MATTER OF LAW, ARE VIOLATED IF THE COURT OF APPEALS DID NOT RULE ON ISSUES OF JURY INSTRUCTIONS ON MATERIALITY AS RAISED ON DIRECT APPEAL AND IN 28 U.S.C. § 2255 PETITION.

Defendants vigorously challenged the materiality of the alleged FD&C Act violations. On the incident involving the alleged addition of sodium hydroxide to the two lots, Defendants argued that the allegedly "degraded" Lactulose was stable, that sodium hydroxide was an approved ingredient in ALRA's formulation, and pointed to an absence of consumer complaints. On the incident involving the use of leaking drums, Defendants introduced unrebutted expert testimony from a distinguished professor of biochemistry that the osmotic pressure and chemical characteristics of Lactulose would prevent the kinds of contamination alleged by the government, and that an FDA inspector had known about the use of the leaking drums, but taken no regulatory action. On the incident involving the K+10 pipe accident, Defendants pointed out that the government's witnesses testified that they tried to get all the metal contamination out of the batch; that at a meeting with ALRA's counsel, FDA representatives had not disputed that using magnets to remove metal contamination was an accepted industry practice: that testing laboratories, including FDA's own, had searched for metal in ALRA's products and found none; and Defendants again pointed to an absence of consumer complaints.

The district court denied Defendants' request for a jury instruction to the effect that materiality was an element of FD&C Act. Tr. 5863, 5866-77, App I

The district court's refusal to instruct the jury that materiality was an element of an "intent to defraud and mislead" under the FD&C Act conflicted with a relevant decision of the Supreme Court, United States v. Neder, 527 U.S. 1(1999).

In spite given two opportunities, once during Direct Appeal and again during a Request for Rehearing and Suggestion for Rehearing En Banc, the 7th Circuit did not resolve the Neder issue. The 7th Circuit opinion did not even address the issue in 266 F.3d 661 (7th Cir. 2001).

Government in its brief filed with the United States Supreme court admitted that the 7th Circuit did not rule on Defendant's appeal on merit. The appellate decision in this case preceded the decision in United States v. Watkins, 278 F.3d 961 (9th Cir. 2002).

3. APPELLANT/PETITIONERS 28 U.S.C. § 2255 PETITION IS PROPERLY FILED AND IT RAISED SUBSTANTIAL CONSTITUTIONAL ISSUES RESULTING FROM CHANGED CIRCUMSTANCES AND SUPREME COURT LAW.

In its written opinion, district court wrote that Court of Appeals on the defendant's direct appeal ruled on issues raised in 28 U.S.C. § 2255 petition and under United States v. Nechy, 827 F.2d 1161, 1164 (7th Cir. 1987), it was bound by the rulings. Mindful of Appellate's earlier reversal of district court's decision on Brady v. Maryland, 373 U.S. 83, 83 S. Ct. 1194, reported as United States v. Bhutani, 175 F.3d 572 (7th Cir. 1999), Honorable Judge Grady, District Court Judge decided to deny any relief requested in Habeas Corpus petition by the defendants. No where in its written opinion, did the District Court Judge explain as to where in the Appellate opinions, did the 7th Circuit rule on the issue of failure to instruct jury on materiality and prosecutors admission to this court that Appellate Court did not rule on materiality instructions dictated by U.S. v. Neder, 527 U.S. 1(1999) and accepted by Department of Justice that Neder decision applies to felony provisions of FD&C Act as explained in U.S. v. Watkins, 278 F.3d 961 (9th Cir. 2002).

Apparently District Court treated 28 U.S.C. § 2255 as successive and applied a modified res judicata rule, a restraint on what is called in Habeas practice 'abuse of the writ'. Felker v. Turpin, 518 U.S. 651, 664, 116 S. Ct. 2333, 135 L. Ed. 2d. 827 (1996).

However for a Habeas petition to be considered successive, the issues raised in prior appeal must have been denied on merits[1]. Absent this, district court must engage in substantive review and not dismiss the petition on procedural grounds. Please see Garrett v. United States, 178 F.3d 940 (7th Cir. 1999) and Bennett v. United States,119 F.3d 470, 471 (7th Cir. 1997).

In this case, the record establishes that the issue of jury instruction on materiality in earlier appeals was not adjudicated on the merits (emphasis added). Here the district court must engage in substantive review as required in O'Connor v. United States, 133 F.3d 548, 550-51 (7th Cir. 1998).

A person when first charged with a crime is entitled to a presumption of innocence and may insist that his guilt be established beyond a reasonable doubt. As a result, the prosecution bears the burden of proving all elements of the offense charged and must persuade the fact finder "beyond a reasonable doubt" of the facts necessary to establish each of those elements. Sullivan v. Louisiana, 508 U.S. 275, 277-278, 124 L. Ed. 2d. 182, 113 S. Ct. 2078 (1993).

---

[1] In its response, government conceded that the petition was not successive, App M .

The Fifth Amendment to the United States Constitution guarantees that no one will be deprived of liberty without "due process of law" and the Sixth, that in all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial by an impartial jury. The Supreme Court has held that these provisions require criminal convictions to rest upon a jury determination that the defendant is guilty of every element of the crime with which he is charged, beyond a reasonable doubt. Sullivan. v. Louisiana, 508 U.S. 275, 277-278, 124 L. Ed. 2D. 182, 113 S. Ct. 2078 (1993).

The jury's constitutional responsibility is not merely to determine the facts, but to apply the law to those facts and draw the ultimate conclusion of guilt or innocence. Id.

The right to have a jury make the ultimate determination of guilt has an impressive pedigree. Blackstone described "trial by jury" as requiring that "the truth of every accusation, whether preferred in the shape of indictment, information or appeal, should afterwards be confirmed by the unanimous suffrage of twelve equals and neighbors...." 4 W. Blackstone, commentaries on the Laws of England 343 (1769).

As Neder and Watkins were decided while this case was still pending and as it announced a new rule of law, the ruling applies to this case. Griffin v. Kentucky, 470 U.S. 314 (1987). It follows that element must be found by the jury under proper instructions. U.S. v. Gaudin, 515 U.S. 506 (1995).

Trial judge's refusal to submit question of materiality to jury violates Federal constitutional right to have jury determine guilt of every element of crime charged. See U.S. v. Gaudin, 515 U.S. 506, 132 L. Ed. 2d. 444, 115 S. Ct. 2310.

In a unanimous decision, Supreme Court held that the trial judges refusal to allow the jury to determine the materiality [of the alleged false statements] infringed the accused's right guaranteed by the Fifth Amendment's due process clause and the Sixth Amendment's right to a jury trial - to have jury determine his guilt of every element of the crime with which he was charged, where the government conceded that the materiality of the alleged [false statements] was an element of the offense. Id. at 445.

Gaudin errors are trial errors subject to harmless error review. In the present case the Gaudin error was not harmless. The record in this case is clear that the jury did not make an independent determination on the issue of materiality. It is not for the District Court to speculate as to what the jury would have decided if the District Court had properly instructed them. Sullivan v. Louisiana, 508, U.S. 275, 281, 113 S. Ct. 2078, 2082-83, 124 L. Ed. 2d. 182 (1993). No matter how convinced the prosecutor or the courts may be on how overwhelming the evidence of materiality, the verdict is flawed. See Raether, 82 F.3d at 193. In fact in this case the government had argued and the Appellate Court has agreed, that the crimes alleged in the counts of conviction did not alter drugs therapeutic efficacy. See United States v.Bhutani, 175 F.3d 578 (7th Cir. 1999) and United States v. Bhutani, 266 F.3d 661 (7th Cir. 2001).

As the Supreme Court instructed in United States v. Gaudin, the district court's decision to remove the issue of materiality from the jury violated appellant's Sixth Amendment right to have a jury determine guilt beyond a reasonable doubt of every element of the crime charged. In this case the prosecutor has the obligation to show that the error was harmless. United States v. Orlano, 507 U.S. 725, 732 113 S. Ct. 1770, 1776-77, 123 L. Ed. 2d. 508 (1993).

Where the trial court fails to instruct the jury as to an element which the government must establish, the conviction is suspect, and must be set aside, unless the government can demonstrate, beyond a reasonable doubt, that "the error did not contribute to the verdict obtained". Neder, 119 S. Ct. at 1837. In this matter, the district court found that the jury verdict "could have gone either way", and the failure of the District Court to instruct the jury about this element of the case was fatal.

In United States v. Neder, the Supreme Court of the United States held that a limited class of fundamental constitutional errors is so intrinsically harmful as to require automatic reversal without regard to their effect on a trial's outcome, such errors infect the entire trial process and necessarily render a trial fundamentally unfair. A jury instruction that omits an element of the offense is one such error. (Citing Sullivan v. Louisiana, 508 U.S. 275, 124 L. Ed. 2d. 182, 113 S. Ct. 2078)

The error either harmless or plain, should be determined in accordance with the law of the time of appeal. See U.S. v. Baumgardner, 85 F.3d 1305 (8th Cir. 1996). The time-of-appeal approach also recognized the principle that a new rule for the conduct of criminal prosecution should be applied retroactively to all cases on direct appeal. See Griffin v. Kentucky, 479 U.S. 314, 328, 107 S. Ct. 708, 716 93 L. Ed. 2d. 649 (1987) See also United States v. Jones, 21 F.3d 165, 173 8 n. 10 (7th Cir. 1994).

The error in this case was substantial and prejudicial. It seriously affected the fairness, integrity or public reputation of the judicial proceedings as Honorable Judge Grady who sat through this trial for 10 weeks and heard testimony from more than fifty witnesses concluded that the verdict could have gone either way.

The purpose of statutory construction is to discern the intent of Congress in enacting a particular statute. The plain meaning of the statue controls. In an earlier Supreme Court decision Fleming v. Florida Citrus Exchange, 358 U.S. 153, 79 S. Ct. 160 the Supreme Court said and we quote:

> "FDCA (21 U.S.C. §§ 301 et seq) is a detailed and thorough piece of legislation whose treatment of many public health and food problems is quite specific, and it is the duty of the courts in construing it to be mindful of its approach in terms of draftsmanship".
>
> "The U.S. Supreme Court in construing the explicit provisions of FDCA (21 U.S.C. §§ 301 et seq) must be sensitive to what congress has written and must recall that its function is to ascertain rather than add, substact, delete, or distort" Id.

In interpreting a statute, court looks first to the plain language of the statue, construing the provision of the entire law, including its object and policy, to ascertain the intent of Congress. United States v. Mohrbacher, 182 F.3d 1042 (9th Cir. 1999).

".....the only duty of the courts is to give it effect according to its terms". U.S. v. Lexington Mills & Elevator Co, 232 U.S. 399, 34 S. Ct. 337.

In light of these issues raised in 28 U.S.C. § 2255 petition the Court must review:

1. Whether the adding of an appoved ingredient sodium hydroxide was a material omission from the batch records cannot be said to have been found by the jury as they were not instructed to make such a finding even though such an omission did not alter drugs safety or efficacy. This omission affects Counts 1, 3, 4, and 6.

2. Whether the possibility of contamination was a material fact in the production of the Lactulose from the leaking drum incident should have been an issue for the jury under proper instruction as well where District Court Judge found that the prosecutors did not prove any actual contamination and when its use was not even concealed from FDA investigators. No materiality instructions concerning these counts were given to the jury. This affects Counts 7 and 8.

3. Whether the possibility of presence of minute particles of metal from an accident in a large volume of powder was a material, effecting the quality of tablets where no actual evidence of contamination existed, should have been a question for the jury. The issue of Materiality was not given to the jury under proper instructions. This affects Count 10.

We submit that the question of materiality affected all of the Counts of Conviction and this Court can not consider the verdict fair and it affects the integrity and public reputation of the judicial proceedings. The error was substantial and prejudicial. Defendants Constitutional rights to a fair trial under the Fifth and Sixth amendments were violated.

4. REFUSAL TO ISSUE A CERTIFICATE OF APPEALABILITY IS CONTRARY TO LAW AS ESTABLISHED BY THIS COURT AND THE COURT OF APPEALS FOR THE SEVENTH CIRCUIT.

In Townsend v. Sain, the Supreme Court of the United States clearly stated that an issue previously raised on direct appeal cannot be relitigated in a Section § 2255 proceeding only if the issue was resolved on the merits. (emphasis added) Townsend v. Sain, 372, U.S. 293, 312-13, 83 S. Ct. 745, 756-57, 9 L. Ed. 2d. 770 (1963). In U.S. v. Mazak, the Court of Appeals for the Seventh Circuit agreed with this opinion where it stated that.... once Court of Appeals has decided the merits of a Ground of Appeals, the decision establishes the law of the case. (emphasis added) U.S. v. Mazak, 789 F.2d 580 (7th Cir. 1986) .

Under Townsend v. Sain, for a court to grant hearings the court must determine:

1. Facts alleged if proved entitle the party to relief.

2. Factual allegations survive summary dismissal because they are not palpably incredible or patently frivolous or false.

3. The factual issues were not previously the subject of a full and fair hearing or fact finding incomplete.

Defendant/Petitioner met each of the three criteria and even offered additional witnesses and testimony to support his claims. Without granting a hearing the District Court simply twisted Petitioners claims and said it agrees with the Government that all three of these issues were decided by the Court of Appeals on the defendant's direct appeals, and that decision of the Court of Appeals are the law of the case.... Clearly this conclusion is flawed because even the Government admits that claims were not decided on merits and U.S. v. Watkins was decided in 2002, after the Court of Appeals ruled in this case.

All of the Substantive counts of conviction occurred prior to November 1, 1989. Application of § 2N2.1(b)(1) conflicts with ex post facto clause of the U.S. Constitution as § 2N2.1(b) was made effective November 1, 1992.

XI. CONCLUSION

The petition for a Writ of Certiorari should be granted.

Respectfully Submitted,

Baldev R. Bhutani

Baldev R. Bhutani, Pro Se
Federal Prison Camp
P.O. Box 1000
Duluth, MN 55814

APPENDIX

TABLE OF CONTENTS

Appendix Page

Seventh Circuit Court of Appeals denies Certificate of Appealability on September 24, 2003. .... A

District Court denies Certificate of Appealability.......... B

District Court denies Defendant's 28 U.S.C. § 2255 petition filed based on changed circumstances and law, dated March 8, 2002. C

Seventh Circuit affirmed Defendant's conviction in a written opinion. 266 F.3d. 661 .... D

Supreme Court denied Certiorari on June 17, 2002. .... E

Seventh Circuits opinion reversing district court's opinion in H, 175 F.3d. 572 .... F

Supreme Court denied Certiorari. 528 U.S. 1161 (February 22, 2000) .... G

District Court opinion granting Defendants a new trial based on violations of Brady v. Maryland. 1997 WL 811689 .... H

Tr. 5863, 5866-77 I

JDistrict Court's finding of facts during sentencing hearing that drugs were not unsafe or ineffective. Tr. 1/24/00 at 39-41 .... J

Tr. 2/15/00 at 121-22 .... K

Sentencing Guidelines for ALRA LABS INC. do not apply as Defendant's conduct did not continue past November 1, 1991. Tr. 6/16/00 L

Jurisdictional Memorandum by United States Attorney, dated January 31, 2003 conceding petitioner's 28 U.S.C. § 2255 petition was not successive.. M

United States Court of Appeals
For the Seventh Circuit
Chicago, Illinois 60604

September 24, 2003
ENTERED: September 24, 2003

Before
Hon. MICHAEL S. KANNE, *Circuit Judge*
Hon. TERENCE T. EVANS, *Circuit Judge*

No. 03-1120

BALDEV R. BHUTANI, *Petitioner-Appellant,*	Appeal from the United States District Court for the Northern District of Illinois, Eastern Division
v.	
	No. 02 C 1817
UNITED STATES OF AMERICA, *Responden- Appellee.*	
	John F. Grady, *Judge.*

ORDER

Baldev R. Bhutani's petition for rehearing, filed on May 9, 2003, is DENIED.

United States Court of Appeals
For the Seventh Circuit
Chicago, Illinois 60604

Submitted March 26, 2003
Decided April 22, 2003
ENTERED: April 22, 2003

Before
Hon. MICHAEL S. KANNE, *Circuit Judge*
Hon. TERENCE T. EVANS, *Circuit Judge*

No. 03-1120

BALDEV R. BHUTANI, *Petitioner-Appellant,*	Appeal from the United States District Court for the Northern District of Illinois, Eastern Division
v.	No. 02 C 1817
UNITED STATES OF AMERICA, *Respondent Appellee.*	John F. Grady, *Judge.*

ORDER

Baldev Bhutani has filed an application for a certificate of appealability. This court has reviewed the final order of the district court and the record on appeal. We find no substantial showing of the denial of a constitutional right. *See* 28 U.S.C. § 2253(c)(2).

Accordingly, the request for a certificate of appealability is DENIED.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

Michael W. Dobbins CLERK Office of the Clerk

Mark Lee Shaw
The Law Office of Mark L. Shaw
33 North County
Suite 302
Waukegan, IL 60085

Case Number: 1:02-cv-01817 Other Court No: 93 CR 585
Title: USA v. Bhutani

ENTERED: December 3, 2002

Assigned Judge: Honorable John F. Grady
MINUTE ORDER of 12/3/02 by Hon. John F. Grady: The defendant Baldev R. Bhutani desires to appeal from this court's order of 11/21/02, denying his motion to vacate his conviction and sentence pursuant to 28 U.S.C. Section 2255. He has applied for a certificate of appealability pursuant to 28 U.S.C. Section 2253(c). The court finds that defendant has not made a substantial showing of the denial of a constitutional right, and, accordingly, the request for a certificate of appealability [7-1] is denied. Mailed notice

This docket entry was made by the Clerk on December 5, 2002

ATTENTION: This notice is being sent pursuant to Rule 77(d) of the Federal Rules of Civil Procedure or Rule 49(c) of the Federal Rules of Criminal Procedure. It was generated by ICMS, the automated docketing system used to maintain the civil and criminal dockets of this District. If a minute order or other document is enclosed, please refer to it for additional information.

For scheduled events, motion practices, recent opinions and other information, visit our web site at www.ilnd.uscourts.gov. Check our web site for CourtWeb--a concise listing of rulings by judges. Check for rulings on noticed motions. Also, subscribe to CourtWatch--a free service--to receive e-mail notification of CourtWeb postings.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES)
OF AMERICA,)
)
v.) 02 C 1817
) 92 CR 585
BALDEV RAJ BHUTANI)
and ALRA LABORATORIES,)
INC.)
Defendants.)

ENTERED: November 21, 2002

ORDER

The defendant Baldev Raj Bhutani has filed a motion to vacate his conviction and sentence in this case pursuant to 28 U.S.C. ¶ 2255. He raises three grounds in his motion:

A. That this court erred in failing to instruct the jury that materiality was an element of the offenses;

B. That this court improperly computed the loss amount involved in the fraud counts for sentencing purposes; and

C. That the defendant is entitled to a new trial because of the government's Brady violation regarding the effectiveness of the lactulose syrup.

In its response to the motion, the government argues that all three of these issues were decided by the Court of Appeals on the defendant's direct appeals, and that the decisions of the Court of Appeals are the law of the case, precluding any reexamination of the issues by this court. United States v. Nechy, 827 F.2d 1161, 1164 (7th Cir. 1987). The defendant has a variety of arguments as to why there has been no final Seventh Circuit decision on any of his issues, but we agree with the government. The Court of Appeals has ruled on each of these matters and we are bound by the rulings. Accordingly, the motion to vacate will be denied.

Defendant also moves for an evidentiary hearing on his motion and for bail. Both of those motions are denied.

Date: November 21, 2002

ENTER: ______________________________
John F. Grady, United States District Judge

U.S. v. BHUTANI

Cite as 266 F.3d 661 (7th Cir. 2001)

UNITED STATES of America,
Plaintiff-Appellee,
v.
Baldev R. BHUTANI and ALRA
Laboratories, Incorporated,
Defendants-Appellants.

Nos. 00-1523, 00-2679.

United States Court of Appeals,
Seventh Circuit.

Argued April 5, 2001.
Decided Sept. 12, 2001.
ENTERED: September 12, 2001

Rehearing and Rehearing En Banc
Denied Nov. 14, 2001.

Following overturn on appeal, 175 F.3d 572, of grant of new trial to defendants who had been convicted of offenses related to manufacture and distribution of mislabeled and/or adulterated pharmaceutical products, the United States District Court for the Northern District of Illinois, John F. Grady, J., on remand for sentencing, denied new motion for new trial. Defendants appealed. The Court of Appeals, Bauer, Circuit Judge, held that: (1) government's position on appeal did not contradict its theory at trial; (2) defendants were subject to criminal penalties despite error which left penalties out of statute during period of offenses; (3) sentencing under guideline for fraud and deceit was proper; (4) sentencing under guideline which went into effect after defendants' offenses was proper; and (5) defendant's gain was appropriate measure of loss attributed to fraud.

Affirmed.

1. Criminal Law 🔑 1192

Government's position on appeal did not contradict its trial theory, and so new trial was not warranted on remand on ground that government's appellate position was newly discovered evidence; government, in prosecution for mislabeling and adulteration of pharmaceutical products, consistently maintained that defendants added sodium hydroxide to liver disease drug for purpose of disguising fact that drug was degrading due to being past its expiration date.

2. Statutes 🔑 241(1)

Generally, courts strictly construe criminal statutes against government and in defendant's favor, so as to ensure that people are fairly warned about what sort of conduct may expose them to criminal penalties and what sort of penalty may be imposed.

3. Statutes 🔑 235

In strictly construing a statute, courts ought not deprive it of obvious meaning intended by Congress, nor abandon common sense.

4. Drugs and Narcotics 🔑 43.1

Defendants' failure to establish or maintain accurate drug manufacturing batch production records in accordance with requirements of Food, Drug, and Cosmetic Act (FDCA) was subject to criminal penalties despite typographical error in amending of statute which apparently eliminated penalties while maintaining requirement for records, during time of defendants' actions; strict reading of FDCA as it was at time of offense put plain language at odds with statute's purpose and intent, and there was no indication in legislative history that in amending FDCA Congress intended to eliminate penalties.. Federal Food, Drug, and Cosmetic Act, § 301(e), 21 U.S.C.A. § 331(e).

5. Criminal Law 🔑 1139

District court's choice of which sentencing guideline to apply is a question of law, and Court of Appeals reviews this choice de novo. U.S.S.G. § 1B1.1 et seq., 18 U.S.C.A.

6. Criminal Law 🔑 1158(1)

Court of Appeals reviews factual determinations for clear error.

7. Sentencing and Punishment 🔑 653(7)

Defendant who was convicted of mislabeling and adulterating pharmaceuticals was properly sentenced under sentencing guideline that applied to fraud and deceit, rather than provision covering violations of drug product regulations; there was substantial evidence of fraud in the case. U.S.S.G. §§ 2F1.1, 2N2.1(a), 18 U.S.C.A.

8. Sentencing and Punishment 🔑 664(4)

Judges must apply the Sentencing Guidelines in force when a defendant is sentenced. U.S.S.G. § 1B1.1 et seq., 18 U.S.C.A.

9. Sentencing and Punishment 🔑 **€736**

Defendant's gain from sale of mislabeled and adulterated drugs was appropriate measure of loss attributed to fraud, for purposes of calculating base offense level for offense involving fraud; consumers bargained for FDA-approved drugs that were in compliance with the law but got drugs that had been mislabeled and adulterated. U.S.S.G. § 2F1.1, 18 U.S.C.A.

10. **Sentencing and Punishment** 🔑 **736**

In calculating loss attributed to fraud for purpose of calculating base offense level, district court is not required to compute the loss with precision; court need only make a reasonable estimate of loss based on information available. U.S.S.G. § 2F1.1, 18 U.S.C.A.

11. Sentencing and Punishment 🔑 **736**

In calculation of loss attributable to fraud, for purpose of calculating base offense level, amount of defendant's gain may provide reasonable estimate of loss if more precise way of measuring loss is unavailable, so long as it has been shown that victims of the fraud suffered loss. U.S.S.G. § 2F1.1, 18 U.S.C.A.

Lawrence G. McDade (argued), Department of Justice, Consumer Litigation, Robert M. Loeb, Department of Justice, Civil Division, Appellate Section, Washington, DC, Barry Rand Elden, Chief of Appeals, Office of the U.S. Attorney, Criminal Division, Chicago, IL, for plaintiff-appellee.

Christopher B. Mead, London & Mead, Douglas B. Farquhar, Hyman, Phelps & McNamara, Washington, DC, for defendants-appellants.

Before BAUER, RIPPLE, and EVANS, Circuit Judges.

BAUER, Circuit Judge.

A jury found defendants Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc. guilty of various violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* The defendants moved for a new trial, which the district court granted, finding that the government violated *Brady v. Maryland,* 373 U.S. 83, 83 S.Ct.. 1194, 10 L.Ed.2d 215 (1963). The government appealed, and in *United States v: Bhutani,* 175 F.3d 572 (7th Cir.1999) we reversed and remanded the case for sentencing. On remand, the defendants again moved for a new trial, which the district court denied. Assuming familiarity with our first opinion, we consider the appeal by the defendants (Neelam does not appeal) from that denial. For the following reasons, we affirm.

A.

[1] The defendants believe that the government's position in the first appeal contradicted its trial theory and that the government's appellate position is newly discovered evidence, and that if the jury had heard the government's appellate theory it would have decided the case differently. Specifically, they contend that at trial the government said that the defendants had added sodium hydroxide to decomposed Lactulose in hopes of concealing its medical ineffectiveness, but on appeal admitted that the Lactulose was medically effective by iterating that it was within the accepted pH range before the addition of sodium hydroxide. On remand, the district court agreed with the

defendants that the government had changed its theory, but the district court refused to entertain the argument, believing that it was foreclosed from doing so since we had held otherwise in our first opinion in this case.

The government counters that its focus at trial was not that the Lactulose was outside of the acceptable pH range or medically ineffective, but rather the fact that the defendants added sodium hydroxide to the Lactulose lots because they wanted the 1986 lots to have a pH similar to the 1988 lots so that they could bear the same expiration date and be sold. The government's position was that the defendants masked the fact that the Lactulose was degrading and past its expiration date in order to make money.

We agree with the government. A second read of the trial transcript reveals that the government's position at trial and on appeal has been consistent. The government did not show at trial that the Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected. The medical efficacy of the Lactulose was only mentioned by the government to explain the significance of expiration dating to the jury. The government wanted to explain why expiration dates are imposed in order to counter the defense theory that the defendants did not intend to put an adulterated product on the market because Lactulose could be stable and medically effective beyond the artificially imposed expiration date assigned by the "paperwork bureaucracy" known as the FDA. The defense again mischaracterizes the thrust of the government's case and regurgitates its argument from the last appeal, the only difference being that in the first appeal they argued that the newly discovered evidence was the U.S.P. recommendation, *see* 175 F.3d at 578-79, and here they point to the government's switch in theories. This supposed difference does not affect our decision. There is no new evidence that would have altered the outcome of this case.

B.

The defendants submit that reversal is justified because the district court abused its discretion, *see United States v. Butler*, 71 F.3d 243, 250 (7th Cir.1995), by permitting the government to elicit impermissibly prejudicial testimony from Dr. John Senior, offered as an expert in gastroenterology and liver disease, *see* Trial Tr. at 1691 (December 28, 1995), about the medical consequences of taking ineffective Lactulose. The defendants claim that Dr. Senior testified that patients could die from ingesting ineffective Lactulose. Before Dr. Senior testified, the district court had admonished the government to avoid introducing this sort of testimony. The defendants believe that the government violated this admonition.

Contrary to the defendants' characterization of Dr. Senior's testimony, the transcript reveals that he did not testify in an impermissibly prejudicial manner. Dr. Senior explained that Lactulose works as a substitute liver for patients with liver disease, and that Lactulose would be ineffective if it had degraded into its component parts because the separate sugars would be absorbed into the small intestine before reaching the colon. He also testified that it would be impossible for a physician to know that Lactulose had degraded to the point of ineffectiveness, and therefore a physician might erroneously determine that the Lactulose was ineffective for a patient for some other reason.

The sole mention of the possibility, of death from ingesting ineffective Lactulose was not presented by the government, but was elicited on cross-examination by the defense:

> Q. [Mr. Branding, Attorney for ALRA] And [Lactulose] doesn't cure the underlying liver disease, does it?
>
> A. Of course not.
>
> Q. It's only-
>
> A. It's only a compensation for a failed organ.
>
> Q. It's used to treat the symptoms?
>
> A. It's used to treat—it's not just symptoms. It's a whole syndrome that may kill. It's not just symptoms.
>
> Encephalopathy due to liver failure may be fatal. It's not just symptoms.

Trial Tr. at 1710-11 (December 28, 1995). The testimony defendants complain about was never offered, and thus there was no abuse of discretion by the district court.

C.

The defendants argue that Count Four, which charged that the defendants "[o]n or about August 12, 1988 with intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the generic drug product, Lactulose Syrup USP" in violation of 21 U.S.C. § 331(e), along with the correlating conspiracy charge in Count One, failed to state a crime for which they could be convicted.

In 1938, Congress enacted the FDCA pursuant to its authority to regulate interstate commerce in order to protect the public from dangerous food and drug products. In 1962, Congress amended the FDCA, adding § 355(j) to require drug manufacturers to establish or maintain records about the manufacture and testing of drugs. *See* The Drug Amendments of 1962, Pub. L. No. 87-781, § 103(a), 76 Stat. 780. Thereafter, the failure to establish or maintain records under § 331(j) was a prohibited act under § 331(e) and subject to the imposition of criminal penalties under § 333, such as imprisonment, fine, or both.

In 1984, Congress amended the FDCA and the federal patent laws to help make available more low cost drugs by creating an abbreviated procedure for FDA approval of generic drug applications. *See* Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585; *see also National Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs.*, 850 F.2d 904, 907 (2d Cir.1988). Congress enacted this new abbreviated drug approval process under § 355(j) and redesignated the old § 355(j) concerning record keeping as § 355(k). However, Congress did *not* alter § 331(e). Thus, § 331(e) still instructed that the failure to establish or maintain records under § 355(j) was subject to criminal penalties, even though the new § 355(j) did not require record keeping. Whether intentional or not, the penalties for failing to establish or maintain records had been in effect eliminated.

In 1990, Congress passed a short, technical amendment, which stated: "Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331(e)). is amended by striking out 'or (j)' and inserting in lieu thereof 'or (k).' " Vaccine & Immunization Amendments of 1990, Pub. L. No. 101-502, 104 Stat. 1285. Thus, by simply replacing "(j)" with "(k)," § 331(e) again clearly subjected violators to the same criminal penalties as they had been for more than two decades prior to 1984 for failing to establish or maintain records.

However, there was a gap between 1984 and 1990 where under the plain statutory language the failure to establish or maintain records under § 355(k) was not subject to criminal penalties. This time gap is of import to this case; the defendants' conduct charged under § 331(e) occurred in August of 1988, which raises the delicate question of whether their convictions for these violations may stand, given that the plain language of the statute did not penalize their conduct. As noted, the defendants argue that under the plain language of the statute they cannot be penalized for failing to establish and maintain records. The government argues that the elimination of the penalty was a scrivener's snafu, and criticizes the defendants' hyper-technical. and illogical reading of the statute. This question has all of the trappings of a law school hypothetical, but with real-world consequences, so although the defendants' brief fails to support this argument with case law discussion or even citation, we nonetheless address this important issue of criminal law and statutory construction.

[2, 3] Generally, courts strictly construe criminal statutes against the government and in the defendant's favor. *See Barrett v. United States,* 423 U.S. 212, 218, 96 S.Ct. 498, 46 L.Ed.2d 450 (1976); 3 Norman J. Singer, SUTHERLAND STATUTORY CONSTRUCTION § 59.03 (5th ed. 1992). This is so to ensure that people are fairly warned about what sort of conduct may expose them to criminal penalties and what sort of penalty may be imposed. *See United States v. Bass,* 404 U.S. 336, 348, 92 S.Ct. 515, 30 L.Ed2d 488 (1971); 3 SUTHERLAND STATUTORY CONSTRUCTION § 59.03. But, in strictly construing a statute, courts ought not deprive it of

the obvious meaning intended by Congress, nor abandon common sense. *See United States v. Moore,* 423 U.S. 122, 145, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975); 3 SUTHERLAND STATUTORY CONSTRUCTION § 59.06.

Some courts have upheld the imposition of criminal penalties despite the presence of a typographical error in the statute. *See United States v. Lacher,* 134 U.S. 624, 625-32, 10 S.Ct. 625, 33 L.Ed. 1080 (1890) (upholding conviction for embezzling a letter containing an article of value under 18 U.S.C. § 318 even though after revision of the statute the wording was altered because "the intention to impose a penalty on [the] commission [of the offense] cannot reasonably be denied; and, although the apparent grammatical construction might be otherwise, the true meaning, if clearly ascertained, ought to prevail"); *United States. v. Graham,* 169 F.3d 787, 790-91 (3d Cir.1999) (upholding a defendant's sentence for illegally reentering the United States after finding that Congress intended that the actual term of imprisonment imposed determines whether a defendant is classified as an "aggravated felon" under 8 U.S.C. § 1101(a)(43) despite the fact that the statutory section was "obviously missing a crucial verb"); *United States v. Warren,* 149 F.3d 825, 827-28 (8th Cir. 1998) (affirming the defendant's sentence of 151 months for manufacturing 32,000 grams of methamphetamine under 21 U.S.C. § 841(b)(1) even though "[a]t the time of [the] offense, because of a typographical error, the same amount of a quantity of a mixture—100 grams—was listed as triggering both the five-year and the ten-year mandatory minimum sentences," because Congress intended drug trafficking penalties to be graduated according to drug quantity); *United States v. Rossetti Bros., Inc.,* 671 F.2d 718, 720 (2d Cir.1982) ("Plainly, Congress did not intend its recodification [of the Interstate Commerce Act] to reduce the reach of [its] penalty, but intended merely to transplant that section, renumbered, into the recodified portion....

Congressional drafters unfortunately overlooked [this], but, when construed in light of the intent of Congress and in light of common sense, that section clearly applies to the regulations here in question."); *United States v. Scrimgeour*, 636 F.2d 1019, 1021–24 (5th Cir. Unit B 1981) (reversing dismissal of indictment under 18 U.S.C. § 1623(d) for making false declarations before a grand jury because in finding Congress' intention in enacting the statute, the court believed Congress inadvertently used an "or" in the statute but meant to use "and"); *United States v. Moore*, 613 F.2d 1029, 1039-45 (D.C.Cir.19 7 9) (same); *United States v. Babcock.* 530 F.2d 1.051, 1053-54 (D.C.Cir. 1976) (holding that, in light of "an inadvertent change" by Congress when reorganizing and renumbering the statute, 2 U.S.C. § 441(b) was not to be interpreted to mean that a misdemeanor violation under § 440 precluded being sentenced to imprisonment); *cf. Whitfield v. Scully*, 241 F.3d 264, 272 (2d Cir.2001) ("Although the statute refers to [28 U.S.C.] § 1915(a)(2) for the manner of payment, we have recognized that this reference is a typographical error (as it makes the statute unintelligible) and that the actual process for payment of costs is instead described in § 1915(b)(2)."); *Estate of Kunze v. C.I.R.*, 233 F.3d 948, 953 (7th Cir.2000) ("The erroneous cross reference in [26 U.S.C. § 7430(c)(4)(D)] to a misnumbered subparagraph in (4)(A) can hardly be construed to have changed the legislative intent . . . or to have affected the substantive rights of the parties. The import of the subsection remains clear, in spite of the typo."); *In re Chateaugay Corp.*, 89 F.3d 942, 952 (2d Cir.1996), (agreeing with other courts that the improperly renumbered subsections in 11 U.S.C. §. 507 were the result of typographical errors by Congress rather than substantive changes in the law).

However, some courts have held otherwise. *See United States v. Faygo Beverages, Inc.*, 733 F.2d 1168, 1170 (6th Cir. 1984) (recognizing that Congress unintentionally eliminated a penalty section in re-codifying the Interstate

Commerce Act, but holding that the defendant was not subject to criminal penalty for his conduct because "it would be unreasonable to require persons confronted with the plain language of a criminal statute to go beyond that statute in order to determine whether Congress really meant what it clearly said"); *United States v. RSR Corp.*, 664 F.2d 1249, 1253–55 (5th Cir.1982) (noting that Congress inadvertently changed a penalty section in recodifying the Interstate Commerce Act, but holding that the defendant was not subject to criminal penalty for his conduct, stating "although this is what Congress clearly meant to say, intended to say, and wanted to say, still Congress did not say it").

[4] While the plain language of the FDCA clearly prohibited the failure to establish or maintain records, criminal penalties were not clearly imposed. Nevertheless, we agree with the reasoning found in the former set of cases rather than the latter because strictly reading and applying the FDCA as it was at the time of the offense in question would put the plain language at odds with the statute's purpose and intent. There is no indication in the legislative history that in amending the FDCA Congress intended to eliminate the penalties. The Law Revision Counsel of the House of Representatives, who prepares and publishes the U.S. Code, even placed a footnote in the 1988 edition of the U.S. Code in § 331(e) after the proscription on failing to keep records under § 355(k), and noted that § 335(j) had been redesignated as § 355(k). Thus, it seems that the failure to cross-reference the sections was interpreted as a mere typo by the Law Revision Counsel. Also, we agree with the government that Congress would not have eliminated the penalties for failing to establish or maintain records in this part of the statute while retaining the penalties for failing to do so under other sections. Furthermore, the government points out that the 1984 amendments broadened the record keeping requirements in the redesignated § 355(k), and that

Congress would not have intentionally broadened the requirements and at the same time have eliminated the penalties for not complying with the requirements.

Finally, the defendants do not argue that because of the typographical error they lacked notice; nor could they since they maintained records believing that they were required to (although they did so inadequately, as this case reveals) under the FDCA. Therefore, we hold that the failure to establish or maintain records under § 355(k) was subject to criminal penalties despite the typographical error in § 331(e) between 1984 and 1990.

D.

[5, 6] Baldev Bhutani also raises several challenges to his sentence imposed under U.S.S.G. § 2F1.1 (2000). "The district court's choice of which guideline to apply is a question of law, and we review this choice *de novo,*" United States v. Andersen, 45 F.3d 217, 219 (7th Cir.1995); we review factual determinations for clear error, *see United States v. Vitek Supply Corp.*, 144 F.3d 476, 490 (7th Cir.1998).

[7] First, the defendant finds error in the district court's choice of guideline tc apply, claiming that he ought to have been sentenced under § 2N2.1(a) rather than § 2F1.1. Section 2N2.1(a) covers violations of statutes and regulations dealing with, among other things, drug products, and assigns a base offense level of six to such violations; however, subsection (b)(1) instructs: "[i]f the offense involved fraud, apply § 2F1.1 (Fraud and Deceit)." Section 2F1.1 "also has a base offense level of six, but provides for substantial increases in offense level based on the amount of loss." *Andersen,* 45 F.3d at 219. Bhutani's argument turns on the notion that § 2N2.1(a) applies because his wrongs were 'knowing, technical" violations of the FDCA, and not as serious as those of other companies that have been prosecuted. This argument is without merit

as there is substantial evidence of fraud in this case. *See, e.g., id.* at 219-20.

[8] Second, he submits that § 2N2.1(b)(1) does not apply to his case since it was made effective on November 1, 1992, but "the offenses of conviction all occurred prior to November 1, 1992." This is of no matter since "judges must apply the Guidelines in force when a defendant is sentenced." *United States v. Perez,* 249 F.3d 583, 584 (7th Cir.2001) (per curiam). Bhutani was sentenced on February 15, 2000, and subsection (b)(1) was then in effect, thus it is applicable.

[9-11] Third, the defendant disputes how the district court measured loss. As noted, sec. 2F1.1 assigns a base offense level of six, which is increased based on the amount of loss attributed to the fraud. In calculating the loss, the district court is not required under the Sentencing Guidelines to "compute the loss with precision; the court need only make a reasonable estimate of the loss based on the information available." *United States v. Duncan,* 230 F.3d 980, 985 (7th Cir.2000); *see* U.S.S.G. § 2F1.1, cmt. 9. If it has been shown that the victims of the fraud suffered a loss and a more precise way of measuring the loss is unavailable, the amount of the defendant's gain may provide a reasonable estimate of the loss. *See Andersen;* 45 F.3d at 221.

Directing us to *United States v. Chatterji,* 46 F.3d 1336 (4th Cir.1995), the defendant maintains that his gain was not the appropriate measure because there was no actual loss to consumers as none of the drugs were shown to be medically ineffective and there was no evidence that anyone fell ill or died. He argues that the calculation should not be based on whether the consumers got what they bargained for, but rather ought to be based on whether the consumers got medically ineffective drugs.

In *Chatterji,* the defendant, sentenced under U.S.S.G. § 2F1.1, submitted two abbreviated new drug applications to the FDA, which were approved. *See id. at* 1338-40. The defendant had submitted false batch records in its application for one of the drugs, and for the other had changed the formula by adding more of an inactive ingredient after its application had been approved without seeking further FDA approval. The district court held that loss should be measured by the defendant's gain from the sale of the drugs because the defendant's fraud voided the FDA. approval, thereby stripping the drugs of market value. *See id.* at 1340. The Fourth Circuit, over dissent, reversed, finding that the defendant's gain was not the appropriate measure of loss because consumers got medically effective drugs that were exactly what they purported to be. *See id.* at 1340-43.

Relying on *United States v. Marcus,* 82 F.3d 606 (4th Cir.1996), the government in our case argues that there was loss to consumers because consumers paid for FDA-approved drugs, but received drugs that were not manufactured according to the FDCA and FDA regulations; therefore, the government argues that the amount of the defendant's gain is an appropriate measure of loss.

In *Marcus,* the defendant, sentenced under § 2F1.1, had obtained FDA approval to manufacture a drug, but changed the formula by adding two additional inactive ingredients without obtaining additional FDA approval. *See id.* at 607-08. The district court found that the defendant's gain was the appropriate measure of loss because the drug did not meet FDA specifications, and therefore, had no value. *See id.* at 608. The court distinguished *Chatterji,* which the Fourth Circuit affirmed, reasoning that the formula modification in *Chatterji* "*was* merely an insignificant change that implicated only the shelf life of the drug," and not the safety or medical efficacy; however, the formula modification here had a bearing on the medical effectiveness, which would require additional testing to determine whether the drug was still safe and effective. *Id.* at 610.

In this case, the district court agreed with the government's position and reasoned:

> I find the analysis in the *Marcus* case from the Fourth Circuit to be persuasive. I understand that the defendants believe *Marcus* is distinguishable on the basis that the defendant there agreed that there was an issue as to whether the drug involved there was the bioequivalent of the patented drug.
>
> I don't regard that as a distinguishing feature of the case, because whether the defendants stipulate to it or not, and certainly they do not in this case, I find that there was an issue as to whether these drugs had been properly manufactured.
>
> I'm not saying that there was an issue as to whether they would be injurious to health or necessarily even an issue as to whether they would be effective for their pharmaceutical purpose. What I find, rather, is that there was an issue as to whether they had been manufactured in such a way that the consumers of those drugs were being sold something other than what they thought they were buying.

> I don't think that any consumer of any of those drugs would have bought those drugs had the consumer known what had happened to them.
>
> * * *
>
> And I think the essence of the loss here to the consumers was the same thing fact [sic] that the *Marcus* case was talking about, namely, the fact that they didn't get the FDA-approved manufactured drugs that they thought they were getting.
>
> And I emphasize that I don't think *Marcus* applies only in the situation where the drugs could be dangerous...

Sentencing Hr'g Tr. at 23-24 (February 15, 2000). The district court based the amount of loss on the defendant's gain, which it estimated at over $200,000, thereby assigning Bhutani a base offense level of fourteen. *See* U.S.S.G. § 2F1.1(b)(1)(I).

While we do not agree with the district court's reading of *Marcus* or his reliance on it, we wholly adopt the core of its rationale. Indeed, we find the district court's reasoning to be more sound than that in *Chatterji* and *Marcus*.[1] The medical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry; rather, the district court was justified in determining that there was a loss because consumers did not get what they bargained for. We agree with the district court's decision that there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law.

---

[1] We decline the defendant's invitation to apply *United States v. Maurello*, 76 F.3d 1304 (3d Cir.1996) by analogy to this case. We also find our decision in *Vitek Supply* inapplicable because it dealt with whether loss to competitors and downstream consumers was to be included in the loss calculation. *See* 144 F.3d at 490-92.

However, the defendant points out that *in Andersen* we held that the defendant's gain was not the appropriate measure of loss when there was "no clear evidence that customers or consumers suffered any loss." 45 F.3d at 221. We so held, in part, because the drugs in that case were sold in hand-labeled containers and the customers were aware that the drugs were not FDA approved. *See* 45 F.3d at 221. That is not so here; here consumers bargained for FDA-approved drugs that were in compliance with the law. This they did not get. We agree with the district court's determination of what constitutes loss in this sort of case, and that the defendant's gain is the appropriate measure of that loss.

E.

The bulk of the defendants' brief is tinged with hyberbole, lamenting that they ought not to have been prosecuted because what they may have done was not so bad compared to what others have done and that their industry is over regulated by the FDA. The judiciary is not the branch to hear these beefs; rather, they ought to be raised with Congress, who makes the law, and prosecutors, who have broad discretion in instituting criminal proceedings. Furthermore, many of the disputes are no more than an invitation to reweigh the evidence based on the defendants' attempt to retry this case on appeal. We are at ease with the jury's work in weighing evidence and assessing credibility and will not engage in second-guessing. The other arguments of the defendants are equally without merit and we shall not address them further.

AFFIRMED.

MEMORANDUM CASES

No. 01-1156. Michael Charles Vinyard, Petitioner v United States.

June 17, 2002. Petition for writ of certiorari to the United States Court of Appeals for the Fourth Circuit denied.

Same case below, 266 F3d 320.

No. 01-1188. Baldev Raj Bhutani and Alra Laboratories, Inc., Petitioners v United States.

June 17, 2002. Petition for writ of certiorari to the United States Court of Appeals for the Seventh Circuit denied.

Same case below, 266 F3d 661.

No..01-1316. City of Seattle, Petitioner v Nick Furfaro, et al.

No. 01-1522. Nick Furfaro, Brandy Kidder, Esmeralda Silva, and JJR, Inc., Petitioners v City of Seattle.

June 17, 2002. Petitions for writs of certiorari to the Supreme Court of Washington denied.

Same cases below, 144 Wash 2d 363, 27 P3d 1160 and 36 P3d 1005

No. 01-1329. Henry Nickell, Petitioner v Memphis Light, Gas & Water Division.

June 17, 2002. Petition for writ of certiorari to the United States Court of Appeals for the Sixth Circuit denied.

Same case below, 16 Fed Appx 401.

No. 01-1233. Christine Mato, Petitioner v Jack Baldauf, et al.

June 17, 2002. Petition for writ of certiorari to the United States Court of Appeals for the Fifth Circuit denied.

Same case below, 267 F3d 444.

No. 01-1234. Jay Cohen, Petitioner v United States.

June 17, 2002. Petition for writ of certiorari to the United States Court of Appeals for the Second Circuit denied.

Same case below, 260 F3d 68.

No. 01-1332. Satellite Broadcasting and Communications Association, et al., Petitioners v Federal Communications Commission, et al.

June 17, 2002. Petition for writ of certiorari to the United States Court of Appeals for the Fourth Circuit denied.

Same case below, 275 F3d 337.

No. 01-1357. Ohio Environmental Protection Agency, Petitioner v Michael D. Nihiser and United States.

June 17, 2002. Petition for writ of cer-

U.S. v. BHUTANI

Cite as 175 F.3d 572 (7th Cir. 1999)

UNITED STATES of America,
Plaintiff-Appellant,
v.
Baldev Raj BHUTANI, Neelam Bhutani, and
ALRA Laboratories, Inc.,
Defendant-Appellee.

No. 98-1154.

United States Court of Appeals,
Seventh Circuit.

Argued Nov. 13, 1998.
Decided April 28, 1999.
ENTERED: April 28, 1999

After they were convicted by jury of offenses related to manufacture and distribution of mislabeled and/or adulterated generic pharmaceutical products, defendants moved for new trial. The United States District Court for the Northern District of Illinois, John F. Grady, J., 1997 WL 811689, granted motion. Government appealed. The Court of Appeals, Bauer, Circuit Judge, held that: (1) government did not violate its *Brady* obligation to disclose evidence when it failed to disclose new stability data for drug at issue in trial, and (2) defendants were not entitled to new trial on grounds of newly discovered evidence, based on new stability data.

Reversed and remanded.

1. **Criminal Law 🔑 1156(1)**

Appellate review of a district court's granting of a new trial in a criminal case is deferential.

2. **Criminal Law 🔑 1139**

Court of Appeals applies de novo review when its review of the granting of a new trial, based on a *Brady* violation arising from government's failure to disclose evidence, revolves around a pure issue of law.

3. **Criminal Law 🔑 700(2.1)**

Government has an affirmative duty to disclose any evidence in its possession that is favorable to the defendant and is material to either the issue of guilt or punishment.

4. **Criminal Law 🔑 700(2.1)**

For purposes of government's *Brady* obligation to disclose material, exculpatory evidence, favorable evidence will be considered "material" if its suppression undermines confidence in the outcome of the trial.

See publication Words and Phrases for other judicial constructions and definitions.

5. **Criminal Law 🔑 700(2.1)**

To establish that government failed to disclose material, exculpatory evidence in violation of *Brady,* defendant does not have to show that it is more likely than not that the verdict would have been different if the evidence in question had been disclosed, but only that there is a reasonable probability that the outcome would have been different.

6. **Constitutional Law 🔑 268(5)**

Any nondisclosure of material exculpatory evidence by the government results in a violation of the defendant's due process rights. U.S.C.A. Const. Amend 5.

7. **Criminal Law 🔑 700(2.1, 6)**

Even though the government has an affirmative duty to disclose exculpatory evidence in its possession, it is not obligated to disclose every possible shred of evidence that could conceivably benefit the defendant, nor does it have an obligation to turn over evidence of which it has no knowledge.

8. **Criminal Law 🔑 700(2.1)**

Government cannot be found to have suppressed evidence if the same information was available to the defendant through the use of reasonable diligence.

9. **Criminal Law 🔑 700(7)**

While the government does not have the duty to disclose information of which it is unaware, if a government agency is charged with the administration of a statute and has consulted with the prosecution in the case, the agency will be considered part of the prosecution, and its knowledge of *Brady* material will be imputed to the prosecution.

10. **Criminal Law 🔑 700(6)**

Government did not violate its *Brady* obligation to disclose material, exculpatory evidence during trial for offenses related to manufacture and distribution of mislabeled and/or adulterated generic pharmaceutical products when government failed to disclose new stability data for drug manufactured and distributed by defendants on which "bible" of pharmaceutical industry relied to publish, posttrial, recommendation to change drug's effective range; possession by Food and Drug Administration (FDA) of stability data from other pharmaceutical companies did not establish knowledge that change would be proposed. U.S.C.A. Const. Amend. 5.

11. Criminal Law 🔑 700(2.1)

To be subject to government's disclosure obligations, *Brady* material must be (1) in the possession of the prosecution, (2) material, and (3) exculpatory.

12. Criminal Law 🔑 700(2.1)

Government cannot be held responsible under *Brady* for failing to disclose merely speculative evidence.

13. Criminal Law 🔑 938(1)

Under four-part test to determine whether defendant's motion for new trial based on newly discovered evidence should be granted, defendant must show that evidence at issue (1) came to his knowledge only after trial, (2) could not have been discovered sooner through use of due diligence, (3) is material and not merely cumulative or impeaching, and (4) would probably lead to acquittal in the event of new trial.

14. Criminal Law 🔑 945(2)

Defendants charged with offenses related to manufacture and distribution of mislabeled and/or adulterated generic pharmaceutical products were not entitled to new trial on grounds of newly discovered evidence, based on post-trial recommendation by industry "bible" to change effective range for one of drugs at issue, despite claim that change destroyed prosecution's theory that defendants adulterated drugs for profit purposes by eradicating need for defendants to spike certain drug lots to show that they remained within effective range, inasmuch as government's theory was not that drugs were or would soon be unfit for use, but that they were adulterated to conceal their age and permit their repackaging with extended expiration dates, and therefore change in effective range was of no consequence.

15. Criminal Law 🔑 940

Even if defendants charged with offenses related to manufacture and distribution of mislabeled and/or adulterated generic pharmaceutical products were en-titled to new trial on charges related to specific drug, based on newly discovered evidence, they were not entitled to new trial on charges pertaining to different drug, given that convictions on those charges were based on entirely different set of facts and conduct, to which new evidence had absolutely no relation.

Susan E. Cox, Office of the United States Attorney, Criminal Division, Chicago, IL, Robert M. Loeb (argued), Department of Justice, Civil Division, Appellate Section, Washington, DC, for Plaintiff-Appellant.

Patrick A. Tuite (argued), Arnstein & Lehr, Steven M. Kowal, Burditt & Radzius, Chicago, IL, for Baldev R. Bhutani.

Steven M. Kowal, Burditt & Radzius, Chicago, IL, for Neelam Bhutani.

Patrick A. Tuite, Arnstein & Lehr, Chicago, IL, for ALRA Laboratories, Inc.

Daniel G. Jarcho, McKenna & Cuneo, Washington, DC, for Amicus Curiae National Pharmaceutical Alliance.

Before BAUER, RIPPLE, and EVANS, Circuit Judges.

BAUER, Circuit Judge.

On February 12, 1996, after a ten week trial, a jury found the three defendants, Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc., guilty of a number of charges related to their manufacturing and distribution of mislabeled and/or adulterated generic pharmaceutical products. After various post-trial motions were denied, the defendants filed a motion for a new trial based on newly discovered evidence and/or the government's violation of *Brady v. Maryland*, 373 U.S.. 83, 83 S.Ct. 1194, 10 L.Ed.2d 215 (1963). The district court granted the defendants' motion for a new trial on all counts of conviction based on the government's violation of *Brady*. The government now appeals that ruling. For the reasons set forth below, we reverse.

I. BACKGROUND

Baldev and Neelam Bhutani are the husband and wife team that owns ALRA Laboratories, Inc., a pharmaceutical company that produces generic prescription drugs. The trial primarily focused on the manufacturing and distribution process of two drugs produced by ALRA—Lactulose and K+10. Lactulose is a drug used to combat advanced liver disease, and K+10 is a potassium supplement.

On January 26, 1994, a federal grand jury filed a superseding indictment charging all three defendants with violations of 21 U.S.C. §§ 331(a), 331(e), 331(k), and 333(a)(2) and Baldev Raj Bhutani and ALRA with violations of 18 U.S.C. §§ 2, 371, 1001, and 1341. The indictment charged all three defendants with (1) adulterating and mislabeling their Lactulose products; (2) keeping improper records with respect to the Lactulose; (3) failing to meet the good manufacturing practice standards; and (4) introducing the adulterated Lactulose into interstate commerce—all with the intent to defraud and mislead. Additionally, all three defendants were charged with adulterating and failing to keep proper records with respect to their K+10 drug. Lastly, Baldev Raj Bhutani and ALRA were charged with providing false statements to various divisions of the Food and Drug Administration ("FDA") and obtaining money through fraudulent schemes. While the trial delved into all of the charges against the defendants, this appeal relates only to a claim of the discovery of new, and the suppression of, evidence regarding the stability of Lactulose and the effect, if any, this had on the rest of the trial.

Lactulose is a drug that comes in a syrup form, much like the consistency of honey, that is used to treat the liver disease portal systemic encephalopathy. When an individual has this condition, the liver is unable to remove excess ammonia before it enters the bloodstream. Lactulose's function is to remove the ammonia from the colon and large intestine before it can enter the bloodstream. Lactulose is a disaccharide, meaning that it is a combination of two sugars. All drugs, including Lactulose, begin a degradation process after they are manufactured, which is why they are given expiration dates. As Lactulose ages, it breaks down into its component parts. Should it eventually decompose fully, a process that may take several years, then it would no longer be Lactulose, as the two sugars will have separated, rendering the drug ineffective. Only when the two sugars are combined may they act to remove ammonia from the colon and large intestine; neither sugar on its own can remove the ammonia. Without Lactulose, a person with portal systemic encephalopathy could slip into a coma caused by excess ammonia in the bloodstream.

One way of testing the stability of Lactulose is to measure its pH level. The pH scale measures the acidity or baseness of a chemical on a scale of 0 to 14. A chemical with a pH below 7 is an acid, while one with a pH above 7 is a base. At the time of the trial, the accepted pH range in which Lactulose was considered most effective, as set forth by the U.S. Pharmacopeia ("U.S.P."), also known as the "bible" of the pharmaceutical industry, was 3.0 to 7.0. The U.S.P. based this determination on stability data provided by various drug manufacturers to the FDA. As Lactulose ages and begins to degrade, it becomes more acidic, i.e. its pH drops. Thus, the older Lactulose gets, the lower its pH reading will become. If the pH level becomes too low, the drug will no longer be effective to fight the liver disease.

The main focus of that portion of the trial concerning ALRA's production of Lactulose centered around two separate lots of the drug: lots 52-230 and 52-231. At trial, the government claimed, and the jury found, that employees at ALRA, at the direction of Baldev Raj Bhutani, adulterated these lots of Lactulose. by "spiking" them with the foreign substance sodium hydroxide in order to conceal their age. Sodium hydroxide is a base, and, when combined with a more acidic substance, will raise its pH level The government introduced evidence that ALRA employeesopened individual bottles of Lactulose from lots 52-230 and 52-231, spiked them with sodium hydroxide, re-sealed the bottles, and repackaged them for distribution with an erroneous expiration date.

Lots 52-230 and 52-231 were manufactured in June of 1986. However, ALRA did not obtain approval from the FDA until July of 1988 to distribute the drug. When ALRA finally received approval to market its Lactulose, it aimed to distribute these two lots of Lactulose by September of 1988. The government presented evidence at trial that lot 52-231 had a pH level of 4.6 in February of 1988 and a pH level of 6.6 in August of 1988. This change represents a 100-fold increase in pH (a chemical with a pH of 4.6 is 100 times more acidic than a chemical with a pH of 6.6). In addition, the government showed that lot 52-230's pH level increased from 4.7 to 5.1 over the same period of time. It was agreed at trial by both government and defense expert witnesses that there is no naturally occurring process which will increase the pH level of Lactulose over time.

Based on the evidence presented at trial, which consisted of expert testimony, testimony from employees of ALRA, and various data findings, on February 12, 1996, the jury found ALRA and Baldev Raj Bhutani guilty with respect to counts 3, 4, and 6 of the superseding indictment—charges relating to adulterating Lactulose, keeping inaccurate records, and sending the adulterated drug into interstate commerce. In total, the jury found ALRA guilty on 8 of 13 counts, Baldev Raj Bhutani on 7 of 13 counts, and Neelam Bhutani on 4 of 10 counts.

On July 5, 1996, after filing various motions for post-trial relief, the defendants filed a motion for a new trial based on newly discovered evidence and/or a *Brady* violation. They claimed that the government, at the time of the trial, had in its possession stability data from numerous drug manufacturing companies that showed that the effective range for Lactu lose was not in fact 3.0 to 7.0, and that Lactulose was still perfectly effective with a pH level as low as 2.5. Furthermore, they asserted that the U.S.P. released a proposal in May of 1996 to change the effective pH range for Lactulose from 3.0 to 7.0 to 2.5 to 6.5. The defendants argued that, under the standards set forth in *Brady,* the government was obligated to turn this information over to them. They further asserted that this new data completely undermines the government's theory of the case that the defendants were willing to put their own personal profits ahead of the safety of the public by putting adulterated drugs on the market. Additionally, they claimed that the government's theory had a prejudicial "spillover" effect in the jury's findings of guilty on all of the counts, even those counts unrelated to the production of Lactulose. Thus, they contend that all of the defendants are deserving of a new trial on all of their convictions.

The district court agreed with the defendants. The court stated that the government's prevailing theme throughout the case was the defendants' blatant disregard for public safety by shipping adulterated drugs into the marketplace just so they would not lose any profits by discarding the old, decomposed Lactulose lots. The court went on to say that since this new stability data showed that Lactulose was still effective at a lower pH level than the government represented at trial, the data tends to show that the defendants would have less of a reason to be nervous about a pH level of 4.6, and, therefore, had no need to spike the product to raise its pH level. Thus, the court determined that the government's suppression of this new stability data "seriously undermines the court's confidence in the verdict of the jury on Counts 3, 4 and 6." *United States v. Bhutani,* 1997 WL 811689 at *14 (N.D.Ill. 1997). In addition, the court found that all of the counts of conviction were so entwined in the government's profit motive theory that it ordered a new trial for all defendants on all of their convictions, even those unrelated to the Lactulose charges. The government now appeals that ruling.

II. DISCUSSION

[1, 2] Appellate review of a district court's granting of a new trial in a criminal case is deferential. *United States v. Boyd,* 55 F.3d 239, 242 (7th Cir.1995). However, when the review of a granting of a new trial based on a *Brady* violation revolves around a pure issue of law, our review is *de novo. United States v. Maloney, 71* F.3d 645, 652-53 (7th Cir.1995), *cert. denied,* 519 U.S. 927, 117 S.Ct. 295, 136 L.Ed.2d 214 (1996).

A. *Brady* Violation

Federal Rule 33 of Criminal Procedure allows a court to grant a defendant's motion for a new trial if it is required in the interest of justice. A motion for a new trial based on newly discovered evidence must be made within two years after final judgment. The district court granted the defendants' motion for a new trial because it found that the government did not fulfill its duties under *Brady* by not disclosing the stability data that was under the control of the FDA. We do not agree that the government committed *a Brady* violation.

[3-6] Under *Brady* and its progeny, the government has an affirmative duty to disclose any evidence in its possession that is favorable to the defendant and is material to either the issue of guilt or punishment. *United States v. Gonzalez,* 93 F.3d 311, 315 (7th Cir.1996). Favorable evidence will be considered material if "its suppression undermines confidence in the outcome of the trial." *Id.* at 316 (quoting *United States v. Bagley,* 473 U.S. 667, 678, 105 S.Ct. 3375, 87 L.Ed2d 481 (1985)). The defendant does not have to show that it is more likely than not that the verdict would have been different if the evidence in question had been disclosed, but only that there is a "reasonable probability" that the outcome would have been different. *Gonzalez,* 93

F.3d at 316 (quoting *Kyles v. Whitley,* 514 U.S. 419, 434, 115 S.Ct. 1555, 131 L.Ed.2d 490 (1995)). Any nondisclosure of material exculpatory evidence by the government results in a violation of the defendant's due process rights.

[7, 8] Even though the government has an affirmative duty to disclose exculpatory evidence in its possession, it is not obligated to disclose "every possible shred of evidence that could conceivably benefit the defendant." *United States v. Hamilton,* 107 F.3d 499, 509 (7th Cir.1997), *cert. denied,* 521 U.S. 1127, 117 S.Ct. 2528, 138 L.Ed.2d 1028 (1997). Nor does it have an obligation to turn over evidence of which it has no knowledge. *Id.* Moreover, the government cannot be found to have suppressed evidence if the same information was available to the defendant through the use of reasonable diligence. *United States v. Morris,* 80 F.3d 1151, 1170 (7th Cir. 1996), *cert. denied, 519* U.S. 868, 117 S.Ct. 181, 136 L.Ed.2d 120 (1996).

[9] While the government does not have the duty to disclose information of which it is unaware, if a government agency is charged with the administration of a statute and has consulted with the prosecution in the case, the agency will be considered part of the prosecution, and its knowledge of *Brady* material will be imputed to the prosecution. *See United States v. Wood.* 57 F.3d 733, 737 (9th Cir. 1995); *United States v. Anderson,* 36 F.Supp.2d 1264, 1267 (D.Kan.1998). "The government cannot with its right hand say it has nothing while its left hand holds what is of value." *Wood,* 57 F.3d at 737.

The material that the defendants claim was suppressed by the government is data that was in the possession of the FDA at the time of trial which said that Lactulose was perfectly stable and effective with a pH level as low as. 2.5. Based on this evidence, the defendants claim that as early as late 1995, the U.S.P. planned to recommend a proposed change in the effective range of Lactulose syrup from 3.0 to 7.0 to 2.5 to 6.5. Therefore, the defendants contend that this information which was in the possession of the FDA was helpful to their case because, had they known of the proposed change, they would have informed the jury of the same and argued that the Lactulose was still effective when the alleged spiking incident occurred. The defendants claim that this evidence undermines the government's theory of the case since the defendants would have had no reason to spike the lots in question. As it turns out, the U.S.P. eventually published its proposal to change the effective pH range of Lactulose in May of 1996, three months after the jury's verdict.

[10-12] While we agree with the defendants that information held by the FDA can, in this case, be imputed to the prosecution, we do not agree that the evidence in question is *Brady* material. *Brady* material must be (1) in the possession of the prosecution; (2) material; and (3) exculpatory. *United States v. Hartbarger,* 148 F.3d 777, 786 (7th Cir.1998), *cert. denied,* -- U.S. --, 119 S.Ct. 1117, 143 L.Ed.2d 112 (1999). We disagree that the evidence in question was in the possession of the prosecution. The real evidence that the defendants rely on in their motion is the eventual publication of the U.S.P.'s proposal to lower the effective range of Lactulose. This was not published until well after the trial had ended. Simply because the FDA had stability data from other pharmaceutical companies does not mean that they had any knowledge that the U.S.P. was going to recommend the proposed change in Lactulose's effective pH range. The government cannot be held responsible for falling to disclose merely speculative evidence. *United States v. Agars,* 427 U.S. 97, 109, 96 S.Ct. 2392, 49 L.Ed2d 342 (1976), n. 16. Since we find that the evidence in question was not within the possession of the government, we need not decide whether it was exculpatory or material. Therefore, we disagree with the district court that the defendants should have been granted a new trial based on the government's alleged *Brady* violation.

B. Newly Discovered Evidence

[13, 14] Even though the evidence in question was not within the possession of the prosecution, the defendants may, nevertheless, be entitled to a new trial based on newly discovered evidence, an alternative theory raised in their motion for a new trial. The standard for determining whether a defendant is entitled to a new trial based on newly discovered evidence is different from that of determining whether one is entitled to a new trial because of a *Brady* violation. We have evolved a four part test to determine whether a defendant's motion for a new trial based on newly discovered evidence should be granted. The defendant must show that the evidence at issue (1) came to his knowledge only after the trial; (2) could not have been discovered sooner through the use of due diligence; (3) is material and not merely cumulative or impeaching; and (4) would probably lead to an acquittal in the event of a new trial. *Gonzalez,* 93 F.3d at 315.

The defendants argue that the U.S.P.'s recommendation to lower the effective range of Lactulose would have been helpful to their case because it would have destroyed the prosecution's profit-motive theory. They argue that since Lactulose does not lose any of its laxative effect and is still effective with a pH as low as 2.5, then there was no reason to spike the lots in question. The district court agreed with them. We find that both the defendants and the district court mischaracterized the prosecution's argument.

The district court's decision relies heavily on the idea that the government portrayed the defendants as profit-hungry monsters who were willing to put the public's safety at risk in order to make a buck by putting ineffective drugs on the market. The court said that the government argued that the defendants spiked their Lactulose lots because they wanted to mask the fact that the product would soon be unfit for use. *Bhutani*, 1997 WL 811689 at *12 (N.D.Ill.1997). Thus, the district court concluded that the new evidence undermines the government's profit-motive theory and the jury could very well have reached a different conclusion had it known of the new effective range.

We agree that the government's theory was that the defendants were driven by the desire to make a profit, but, after reviewing the trial transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit, or close to unfit. What the government did argue was that the defendants spiked the Lactulose lots because the lots were old and they wanted to conceal their age to make them look like newer lots of Lactulose produced by ALRA. The reason for this is that the FDA has determined that Lactulose should be marketed with an expiration date that is 18 months after its manufacture. Here, the lots in question were all manufactured in 1986 and not distributed until 1988. In order for the defendants to sell their product, it had to conform to FDA standards. Thus the defendants had to conceal the *age* of the product. They did this by raising the pH levels and marking the lots with expiration dates of September 1989. The government did not argue that the pH level in the lots in question ever dropped below 3.0. In fact, when the government's expert witness, Dr. Hicks, was questioned by defense counsel, he stated that the pH levels were never outside of the effective range. Thus, it was the defense, and not the government, that put the effective range at issue in the first place. Neither Dr. Hicks, nor any other government witness, ever testified that the Lactulose in question was ineffective. The adulterated lots had the potential of becoming unsafe while in the marketplace with an inaccurate expiration date, but were not necessarily unsafe at the time of distribution. The government argued that the defendants put the public's safety at risk by supplying adulterated products, not necessarily ineffective ones.

Throughout the trial, the defendants contended that the spiking incident never occurred. However, based on all of the evidence, the jury simply believed the prosecution's case over the defendants'. The prosecution presented expert witnesses who testified that there is no naturally occurring process which can reverse the trend of Lactulose's degradation. In addition, the government called former employees who participated in the spiking incident to describe the process that was used in adding the sodium hydroxide to the Lactulose syrup. Those employees described, in detail, the "assembly line" type procedure that was used in opening the Lactulose bottles, injecting them with sodium hydroxide with a turkey baster type instrument and later a syringe, re-sealing the bottles, and re-packaging them with falsified expiration dates. The government also presented employee time cards with extensive overtime recorded on the days the spiking incident occurred. Lastly, these employees testified that Baldev Raj Bhutani oversaw and authorized the entire operation. The defense had ample opportunity to cross examine these witnesses, and indeed they did. The fact that the U.S.P. subsequently proposed a lower effective pH range for Lactulose is of no consequence to the case since the government never argued that the Lactulose's pH was outside of the effective range, or even close to being outside the range.

The trial judge properly instructed the jury on what it must unanimously find in order to convict the defendants on counts 3, 4, and 6. Count 4 charged that the defendants, with the intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the Lactulose lots in question. In order to find the defendants guilty of this count, the jury had to unanimously find that the defendants injected the lots with sodium hydroxide. The jury unanimously found this with respect to Baldev Raj Bhutani and ALRA, but not Neelam Bhutani. For count 3, the jury had to find that the lots of Lactulose were adulterated. The judge instructed the jury that the drug could have been adulterated in one of three ways. First, it could have been produced in a way that did not conform with the good manufacturing practices. Second, it could have decomposed to such a point that it no longer met applicable testing specifications. Third, the defendants could have added sodium hydroxide to it. The jury only had to find one of those three events occurred for the drug to be adulterated. The same is true for count 6.

Arguably, the new proposal by the U.S.P. could have shown that the Lactulose still met specifications even though it had degraded some. However, since the jury found in count 4 that the defendants added sodium hydroxide to the Lactulose, then it implicitly found that the drug had been adulterated with respect to counts 3 and 6 as well. Its finding in count 4 acts as an independent basis for a finding of adulteration for counts 3 and 6. Therefore, while the new data could show that the Lactulose had not degraded to the point of making it unsafe, the jury nonetheless found that the drug was adulterated by the addition of sodium hydroxide. Thus, the defendants are not entitled to a new trial for counts 3, 4, and 6 based on newly discovered evidence.

C. The Spillover Effect

[15] Lastly, the district court ruled that all of the defendants were entitled to a new trial on all of their convictions, even those unrelated to Lactulose, because all of the charges were so entwined with the government's profit-motive theory that it influenced the jury's decision on the other counts. Since we have determined that the defendants are not entitled to a new trial for counts 3, 4, and 6 because of the new evidence, it necessarily follows that there could be no spillover effect on the other counts. Even if we were to find that the defendants were entitled to a new trial for the Lactulose charges, the other convictions were based on an entirely different set of facts and conduct for a different drug altogether. These convictions were based on the manufacturing of K+10 and how a foreign substance was accidentally introduced into the mixing process, yet the drug entered the marketplace regardless. Even if the new evidence would have led to a different outcome in counts 3, 4, and 6, the new evidence has absolutely no relation to the conduct for which the defendants were found guilty in the manufacturing and record keeping of K+10. These violations contain completely different elements and are not related to the U.S.P.'s new proposal whatsoever. The jury found beyond a reasonable doubt that the defendants were guilty of these counts regardless of the Lactulose charges as evidenced by the fact that it did not find that Neelam Bhutani was guilty of counts 3, 4, and 6, but that she was guilty for her role with respect to the K+10 offenses. Therefore, the defendants are not entitled to a new trial on these additional counts.

III. CONCLUSION

For the reasons set forth above, we REVERSE the district court's ruling that the defendants are entitled to a new trial on all of their convictions based on a *Brady* violation or newly discovered evidence and REMAND to the district court with orders. to reinstate the verdicts of conviction and to sentence the defendants to appropriate terms as prescribed by the Sentencing Guidelines.

U.S. SUPREME COURT REPORTS

No. 99-1118. Kamel Patel, Petitioner v United States.

528 US 1161, 145 L Ed 2d 1082, 2000 US LEXIS 1117; 120 S Ct 1173.

February 22, 2000. Petition for writ of certiorari to the United States Court of Appeals for the Fifth Circuit denied.

No. 99-1119. Richard M. Patterson, Petitioner v United States.

528 US 1161, 145 L Ed 2d 1082, 2000 US LEXIS 1118, 120 S Ct 1173.

February 22, 2000. Petition for writ of certiorari to the United States Court of Appeals for the Fourth Circuit denied.

Same case below, 178 F3d 1288.

No. 99-1126. Mauricio Raul Guzman, Petitioner v Texas.

528 US 1161, 145 L Ed 2d 1082, .2000 US LEXIS 1121, 120 S Ct 1174.

February 22, 2000. Petition for writ of certiorari to the Court of Appeals of Texas, Fourth District, denied

Same case below, 993 SW2d 232.

No. 99-1127. Eastman Kodak Company, Petitioner v Myrtle Thomas.

528 US 1161, 145 L Ed 2d 1082, 2000 US LEXIS 1122, 120 S Ct 1174.

February 22, 2000. Petition for writ of certiorari to the United States Court of Appeals for the First Circuit denied.

Same case below, 183 F3d 38.

No. 99-1120. Baldev Raj Bhutani, et ux., and Alra Laboratories, Inc., Petitioners v United States.

528 US 1161, 145 L Ed 2d 1082, 2000 US LEXIS 1119, 120 S Ct 1173.

February 22, 2000. Petition for writ of certiorari to the United States Court of Appeals for the Seventh Circuit denied.

Same case below, 175 F3d 572

No. 99-1121. Hector V. Luna, Petitioner v County of San Bernardino, et al.

528 US 1161, 145 L Ed 2d 1082, 2000 US LEXIS 1120, 120 S Ct 1174, reh den 529 US 1095, 146 L Ed 2d 655, 2000 US LEXIS 2856, 120 S Ct 1737.

February 22, 2000. Petition for writ of certiorari to the United States Court of Appeals for the Ninth Circuit denied.

Same case below, 165 F3d 35.

No. 99-1128. Ben J. Tomeo, Petitioner v Honeywell International, Inc., et al.

528 US 1161, 145 L Ed 2d 1082, 2000 US LEXIS 1123, 120 S Ct 1174, reh den 529 US 1083, 146 L Ed 2d 512, 2000 US LEXIS 2544, 120 S Ct 1711.

February 22, 2000. Petition for writ of certiorari to the United States Court of Appeals for the Second Circuit denied.

No. 99-1138. Jean. Rosenbaum, Petitioner v Kurt Rosenbaum.

528 US 1161, 145 L Ed 2d 1082, 2000 US LEXIS 1124, 120 S Ct 1174, reh den 529 US 1083, 146 L Ed 2d 512, 2000 US LEXIS 2545, 120 S Ct 1711.

February 22, 2000. Petition for writ of certiorari to the Appellate Court of Illinois, First District, denied.

Same case below, 185 Ill 2d 666, 242 Ill Dec 150, 720 NE2d 1105:

UNPUBLISHED

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

UNITED STATES OF AMERICA,)
Plaintiff,)
)
v.) No. 93 CR 585
)
BALDEV RAJ BHUTANI;)
NEELAM BHUTANI, and ALRA)
LABORATORIES, INC.,)
Defendants.)

ENTERED: December 16, 1997

MEMORANDUM OPINION

Pending before the court is "the Motion of the Defendants for a New Trial Based on Newly Discovered Evidence and/or Violation of Brady v. Maryland." The motion will be allowed, for the reasons explained in this opinion.

Procedure

The defendants in this case are Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc., a corporation Baldev and Neelam Bhutani own and operate. ALRA is in the business of manufacturing and distributing generic drug products. The indictment included allegations that the defendants conspired to commit and did commit certain offenses involving adulteration and misbranding of various

* * *

* * *

will be absorbed in the small intestine and never reach the colon.[3]

Lactulose which is in its optimal, disaccharide condition is said to be "stable." A way of testing the stability of the solution is to determine its "pH" level, that is, its point on the range between acid and base. The scale runs from 0 to 14, with 7 being considered neutral. The lower the pH, the more acidic the solution will be. At some level, a pH reading will be so low as to indicate a breakdown of the Lactulose into its constituent monosaccharides. According to the testimony of Dr. Hicks, Lactulose is "optimally stable at somewhere between a pH of 4 to 5."[4]

The government's contention at trial was that defendants' Lactulose lots in question were old and had become unstable or dangerously close to being unstable, so that they were either medically ineffective or close to becoming medically ineffective. It was for this reason, according to the government, that defendants injected these aged Lactulose lots with Sodium Hydroxide, a base, in order to raise the pH of the Lactulose and make it appear safe for use. Adding pH to decomposed Lactulose would not, of course, restore it to its disaccharide form; it would merely mask the fact that the decomposition had occurred.

The motive was profit, said the government. The defendants did not wish to discard the decomposed Lactulose, so they disguised it in order to make it saleable. This theme of cutting corners and making profits in disregard of public health was emphasized to the jury as early as the prosecutor's opening statement:

---

[3] Testimony of Kevin Hicks, p. 34.

[4] Id., p. 34.

This is a case. about a pharmaceutical company that put contaminated drug products on the market and lied to the Food and Drug Administration about it. It is about the decisions of the company's president and a company's quality control director to violate the rules governing the pharmaceutical industry. It is about their decisions to cut corners in the manufacturing and in the testing of human pharmaceuticals and to put adulterated and misbranded prescription drug products on the market.

Why? To make money. Because cutting corners saved money and selling defective products raised their own profits. This case is about a corporation and its two officers' repeated decisions to put their personal profit ahead of the public health, and their decisions to line their own pockets instead of ensuring that patients, their customers, were receiving safe and effective prescription medication.

* * *

Again, why did they do this? To make money. This case is about a corporation and its officers' repeated decisions to put money over the quality of their product, to line their own pockets instead of ensuring that their customers were taking safe and effective medicine and to put their private profit over the public health.

* * *

Now through the next few weeks, the government will not attempt to review with you everything that happened to ALRA over a five-year period. We won't tell you what happened each and every day. But what we will do is we will bring witnesses before you, former employees of Alra, who will tell you about some of the things that went wrong at the firm. We will tell you what happened on those occasions when Baldev Raj Bhutani and Neelam Bhutani chose to break the rules and when they directed their employees-to ignore the ANDA [ABBREVIATED NEW DRUG APPLICATION] procedures and violate the CGMP [CURRENT GOOD MANUFACTURING PRACTICES] regulations and when they allowed defective products to enter the market.

Over the next few weeks we will present to you six incidents, and the incidents document what went wrong at the firm, what violations occurred.

The first incident that you will hear about involves a drug product called Lactulose, and Lactulose is a prescription drug. It is a liquid and it comes in 8 and 16 ounce bottles and is used for patients who have a disease called portal systemic encephalopathy. And it is essentially people who have extensive liver disease or liver failure. And the product is used to draw contaminants out of the body and to prevent coma. That is what it says on the label.

* * *

That is not all they did. Before they shipped the product out the door, they took another important step to cover up the fact that they were shipping expired product. Oftentimes large buyers or wholesalers of generic drug products will test a product once it has been received, and they will test a product like Lactulose for something like pH or acidity, and these tests are designed to assure that the product is not degrading, that it is still within specification.

Baldev Raj Bhutani and Neelam Bhutani knew this. In fact, ALRA was selling these products to large pharmaceutical wholesalers including the AARP and Biolab.

So what do the Bhutanis do? The defendants instructed their employees to open up the bottles of Lactulose, those 1986 bottles, and inject a chemical called sodium hydroxide into the bottles in order to raise the pH and make it appear that the product had not, in fact, degraded.

They added this undocumented component through an unapproved procedure to mask or to hide the underlying degradation of the product. So even when a diligent consumer like a wholesaler might test a product, they could not know that the product had degraded, and the expiration date the defendants had put on the label was a lie. The defendants chose to label a product with an expiration date more than three years after its date of manufacture even though they knew the product was only approved for 18 months. They injected a chemical into the product to mask the fact that the product had degraded.

Why? Because destroying the product would cost money, and selling the expired product would make money. Now, that is what the government will show you with respect to this first incident, and you will see proof in documents and you will hear the evidence through the testimony of witnesses.

You will first hear from Dr. Kevin Hicks, and he is the carbohydrate chemist. He is an expert on Lactulose, and he will tell you that Lactulose is a type of carbohydrate called a disaccharide, and this disaccharide degrades over time. And as time passes, the product breaks down into its component parts. And you can detect this degradation of the product by testing its pH. And as the product degrades, the pH will decrease.

And Dr. Hicks will tell you that adding the chemical, sodium hydroxide, before shipping a product out would simply mask or hide the degradation. It would not reverse it. It would not make the product new again.

In addition, another expert, Dr. John Senior, the gastroenterologist, will tell you that he treated hundreds of patients with this disease of portal systemic encephalopathy, the liver failure, and that he prescribes Lactulose to treat patients. He will tell you that if a product is sufficiently old and the

> disaccharide has degraded in to its component products, the Lactulose simply will net work. The drug will be ineffective in treating the patient's advanced liver disease. And a physician may have to resort to other measures to prevent coma.[5]

At trial, the government called a number of former ALRA employees who testified that at the direction of the Bhutanis, they injected sodium hydroxide into bottles of Lactulose Syrup, using syringes. The Bhutanis denied on the witness stand that any such thing occurred.

On the question of whether the Lactulose in question was likely to have been medically ineffective at the time it was shipped, the government elicited the following testimony from Dr. Senior:

> Q. Does the Lactulose have to be in the disaccharide form in order to work?
>
> A. Of course. If its not in the disaccharide form it's not Lactulose.
>
> Q. If Lactulose is degraded into monosaccharide components, would it work to treat portal systemic encephalopathy?
>
> A. No, it won't work if its degraded or split because the split products of Lactulose are fructose and galactose, which are easily-absorbed sugars. They're gone; they never get to the colon.
>
> Q. So, if the Lactulose has been split before you give it, it will not reach the colon.

---

[5] Smolover Opening Statement, pp. 4-5, 12-14, 16-17, 20-21.

A. Well, of course. I mean, if the Lactulose is effective it is Lactulose. If it's not Lactulose, then it doesn't work.

Q. Conversely then, would Lactulose be less effective if it had broken down, or a substantial portion had been broken down?

A. Of course it would be less effective if it had been broken down. Of course.

Q. Would lactulose, if it had degraded into its component parts, be effective in treating portal systemic encephalopathy?

A. No, it would not.

Q. Why would that be?

A. Because the degraded products would not reach the colon; they would be absorbed by the small intestine before the material reached the colon. So the bacteria in the colon would have nothing to work on. So they could not acidify, they could not cause a laxative effect.

Q. And would a physician be able to ascertain what was wrong if Lactulose had broken down intoits disaccharide form?

A. That makes it very hard on the physician, because a lot is going on in these sick patients. They have got a failing liver, theyoften have -- they are now getting failure of the brain function, they often have kidney failure that goes with the liver failure.

> They've got a lot of problems. And the last thing a physician is going to think of when he prescribes a drug is it isn't what it's supposed to be. That's not something that would occur to a physician right away. He would not quite know what to do if it wasn't working.[6]

The prosecutor in her closing argument drove home to the jury this testimony of Dr. Senior as demonstrating the dangerousness of the Lactulose that had been injected with the Sodium Hydroxide:

> Now, after you heard about all the chemistry, you heard from a physician, and that was Dr. John Senior. And he told you the medical consequences of this degradation and - why in very human terms, this all matters.
>
> Dr. Senior was that gastroenterologist who has practiced for 30 years. And he explained to you that Lactulose is used to treat a condition called portal systemic encephalopathy. It's basically a condition resulting from serious liver disease. And he told you about his experience treating 3,500 patients.
>
> He explained to you that in patients with this condition in their livers, their liver stops to function because the liver cannot remove the ammonium from the blood; and, without intervention, the ammonium in the blood reaches the brain, compromises brain function and can cause coma and sometimes death.

---

[6] Testimony of Dr. John Senior, pp. 27-29.

Lactulose is used to substitute for a healthy liver. Lactulose works in the colon, the large intestine, to bind with the ammonium and excrete it before it can enter the bloodstream.

But as Dr. Senior pointed out, the Lactulose has to reach the large intestine in order for it to work. If the Lactulose is already broken down, if it is already degraded into its monosaccharide form, the monosaccharides will be absorbed in the small intestine, they'll be digested, and the Lactulose in its disaccharide form will never reach the colon, the site of the therapeutic treatment. And it will be rendered ineffective in treating patients with hepatic coma or portal systemic encephalopathy.

And Dr. Senior told you that a physician would not surmise that something was wrong with the Lactulose. They'd be forced to switch to another therapy, another treatment, that could potentially pose more risk.

And Dr. Senior pointed out that the less concentrated the Lactulose, the less disaccharide form of the Lactulose in that bottle, the less effective it's going to be in treating the disease condition for which it should be used: portal systemic encephalopathy.

Now, you've heard all this evidence about the reworking of the batches. You have heard all these -- witness after witness tell

> you about the sodium hydroxide injection. You've heard about the labeling of September '89, where that date came from and how it was put on the bottles.
>
> And we've talked to you about the motive in committing these crimes. The lots were reworked because the defendants didn't want to lose money and throw these expired lots away. They injected the chemical to mask the degradation, so the consumer would not know that the product has degraded.
>
> They failed to document the rework in the batch records, so that the FDA, when examining the records, wouldn't know what had happened.
>
> And they put a label on the product that was more than three years after the date of manufacture, even though they knew that the appropriate expiration date at any time was not more than 18 months.
>
> And they did so to raise money, because destroying that old product would cost them money and selling expired product would raise profits.[7]

The government's "Version of the Offense" which the prosecutors submitted to the probation officer for inclusion in the presentence report shows that the government believed it had proved the defendants had injected the sodium hydroxide to conceal the medial ineffectiveness of the Lactulose:

---

[7] Smolover closing, pp. 40-42.

> The expert testimony of a carbohydrate chemist and gastroenterologist at trial indicated that these lots posed a risk to the public health, as degraded Lactulose will not be effective in treating portal systemic encephalopathy. Left untreated the condition can be life threatening.[8]

The government went on to state its position that the defendants should receive a 2 point enhancement under sentencing Guideline 2F1.1(b)(4) because the offense "involved the conscious risk of serious bodily injury:"

> The Government's gastroenterology expert testified that Lactulose is used to treat a condition called portal systemic encephalopathy, caused by advance liver failure. The Lactulose must reach the colon in its original disaccharide form in order to bond with ammonium and rid the system of this toxin. If the Lactulose has degraded it will break into monosaccharides and be absorbed in the small intestine. It will not reach the colon at all. The ammonium, in turn, will remain in the blood, reach the brain, and may cause hepatic coma or even death. The expert further testified that a physician treating a patient with this condition is unlikely to presume that the Lactulose is defective. The doctor is thus likely to employ more radical drug therapy in attempting to treat the portal systemic encephalopathy and resulting coma. Finally, the defendant's own chemistry expert testified that the injection of sodium

---

[8] Government's Version of the Offense submitted as to the defendant ALRA, dated April 22, 1996, p. 9. (Identical statements were submitted for the two individual defendants).

> hydroxide itself can pose significant risk to those consuming the product and the chemical may exist in a concentrated form in pockets of the liquid and may be lethal.[99]

The Pretrial Discovery

Extensive pretrial discovery motions were filed by the defendants. The court had the impression from the government's representations that it was furnishing everything the defendants were entitled to, and more. At one point the government filed a response stating that

[f]or over fifteen months, the government has complied with, and far exceeded, its discovery obligations under Rule 16 of the Federal Rules of Criminal Procedure and Local Rule 2.04. The government promptly turned over all Brady material and provided the Defense with access to and copies of, all records in the possession of government counsel to which the Defense was even remotely entitled.[10]

The Response went on to state that

> (a]ll Brady (i.e., potentially exculpatory) material has been produced. In making its Brady production, the government has taken a very expansive approach and produced any materials that are simply "favorable" to the Defense, even if not 'exculpatory.' Of course, the government recognizes its continuing obligation under

---

[9] Id. at 16-17.

[10] Government Collective Response filed August 23, 1995, at 2.

> Brady and will produce any additional materials of which the government becomes aware.[11]

THE DEFENDANTS' MOTION

The evidence at trial was that the pH range recommended for Lactulose by the U.S. Pharmacopeia ('U.S.P.') was between 3.0 and 7.0. The recommendation by the U.S.P. is based on stability data made available to it by drug manufacturers. The same data is submitted by the manufacturers to the U.S. Food and Drug Administration, the agency which investigated this case and worked closely with the Department of Justice throughout its prosecution.

The verdict of the jury was returned on February 12, 1996. In June of 1996, the U.S.P. issued a bulletin that proposed revision of the pH range downward from 3.0-7.0 to 2.5-6.5. The explanation given by U.S.P. for the proposed change was that:

> Based on information received that stability data has shown a downward trend in pH over time, it is proposed to revise the pH range in this monograph. The proposed pH range is reported not to have any significant impact on the safety and quality of this product: it does not in any way effect the laxative properties of the product, and it does not affect the level of the related substances.

Based on this information, the defendants filed the present motion, contending that the stability information should have been disclosed to the defendants inasmuch it undercut the government's contention that the Lactulose involved in Counts 3, 4, and 6 was at or near the point of medical in-effectiveness at the time it was distributed by the defendants:

---

[11] Id. At 9.

> Specifically, it was alleged and repeatedly argued that, because the pH of the lactulose syrup that had been manufactured in 1986 was dropping close to a level 3, such lactulose was in fact decomposed and thus, the therapeutic effects of the lactulose were being lost and the health of consumers was therefore jeopardized. It was the Government's position that, as the pH dropped below 3, certain portions of the lactulose or its parts were being dissipated to impact quality. Thus, it was theorized that if a patient was not responding well to lactulose treatment, a physician had no way of knowing whether it was from the patient's condition or whether the lactulose was no longer effective.
>
> Accordingly, the Government's thrust was not merely to demonstrate that sodium hydroxide, an approved additive, was added to the lactulose in 1988, but to prove that the addition of sodium hydroxide was to mask lactulose decomposition, thereby endangering the lives and safety of the consumer simply to profit the Defendants. However, recently discovered evidence not only provides significant support for the Defendants' position that the lactulose was safe, but also demonstrates that the

> Government knew it was safe and still argued the contrary to the jury and this Court.[12]

The motion has been pending for a considerable period of time, due in part to the fact that, over the government's objection, the court allowed the defendants' discovery in connection with the motion and required the government to produce the stability records filed with the FDA by the Lactulose producers for the years underlying the U.S.P. proposal. These stability records do indeed support the proposal and demonstrate that Lactulose with a pH as low as 2.5 is stable and medically effective. The government does not contend otherwise, nor does it even contend that the FDA was unaware of the contents and significance of these records prior to trial. However, it makes a variety of arguments as to why, as a matter of law, the defendants are not entitled to a new trial.

THE LEGAL ARGUMENTS

Defendants have moved for relief under Brady v. Maryland and Rule 33 of the Federal Rules of Criminal Procedure. The parties have not specifically addressed the question of which test applies in the event there are any differences between Rule 33 and Brady. The defendants rely mainly on cases decided under Brady, while the government's emphasis is largely on cases decided under Rule 33. There is a difference between the two approaches, and it will be useful to point out that difference before proceeding to a discussion of the parties' arguments.

Federal Rule of Criminal Procedure 33 permits a defendant to request a new trial based on "newly discovered evidence." See Fed. R. Crim. P. 33 (stating that "[a] motion for a new trial based on the ground of newly discovered evidence" may be made before or within two years after final judgment). In most cases, a defendant making such a request "must satisfy a stringent multi-stage test." United States v. Gootee, 34 F.3d 475, 479 (7th Cir. 1994). The defendant must show that the evidence in question (1) came to his knowledge only after trial; (2) could not have been discovered sooner through the exercise of due diligence; (3) is material and not merely impeaching or cumulative; and (4) would probably lead to an acquittal in the event of a new trial. United States v. Gonzalez, 93 F.3d 311, 315 (7th Cir. 1996); United States v. Severson, 49 F.3d 268, 271 (7th Cir. 1995); United States v. Young, 20 F.3d 758, 763 (7th Cir. 1994). This multi-part test is also known as the "Berry rule," since it was first articulated in a state court case of the same name over 100 years ago. 3 Charles Alan Wright, Federal Practice and Procedure § 557, at 315 (2d ed. 1982 & Supp. 1997) (citing the 1851 Georgia case of Berry v. State).

---

[12] Memorandum in Support of Motion for New Trial Based on Newly Discovered Evidence and/or in Violation of Brady v. Maryland, pp. 1-2.

Significantly, however, the Berry rule applies only to "ordinary" motions for new trials based on claims of newly discovered evidence. Id., at 316. Different, less restrictive rules apply if a motion for a new trial is based on a claim of nondisclosure or suppression of evidence by the prosecution. Id.; See also id., § 557.2, at 352-53 (" [A] situation in which it is clear that the Berry rule does not apply is where the government has failed to disclose evidence favorable to the defense."). As a result, a Rule 33 motion containing a "suppressed evidence" claim is governed by the standards set forth in Brady v. Maryland, 373 U.S. 83 (1963), and its progeny. See United States v. Kelly, 790 F.2d 130, 133 (D.C. Cir. 1986) (specifically acknowledging that the Berry rule "does not . . . govern motions for a new trial when the newly-discovered evidence indicates that the original trial was marred by a sixth amendment or Brady violation"). Most federal cases do not expressly discuss the difference between "ordinary" Rule 33 motions and Rule 33 motions based on Brady, but the cases at least implicitly recognize the distinction by applying Brady in lieu of the Berry rule. See, e.g., Gonzalez, 93 F.3d at 315-16; United States v. Veras, 51 F.3d 1365, 1374-75 (7th Cir.), cert. denied, 116 S. Ct. 540 (1995) ; Young, 20 F. 3d at 764; See also, e.g., United States v. Wong, 78 F.3d 73, 79 (2d Cir. 1996); United States v. Thornton, 1 F.3d 149, 158 (3d Cir. 1993); United States v. Stephens, 964 F.2d 424, 435-36 (5th Cir. 1992).

The criteria for relief under Brady are as follows. A defendant must establish that (1) the prosecution suppressed evidence; (2) the evidence was favorable to the defense; and (3) the evidence was material to an issue at trial. United States v. Morris, 80 F.3d 1151, 1169 (7th Cir.), cert. denied, 117 S. Ct. 181 (1996); United States v. Payne, 102 F.3d 289, 293 (7th Cir. 1996) (both citing United States v. Silval, 71 F.3d 667, 670 (7th Cir. 1995)). Evidence is considered "material"

> if there is a reasonable probability that the disclosure of that evidence to the defense would have changed the result of the trial. There is a reasonable probability of a changed result where the government's suppression of evidence "undermines confidence in the outcome of the trial."

Payne, 102 F.3d at 293 (quoting Kyles v. Whitley, 115 S. Ct. 1555, 1556 (1995) and United States v. Bagley, 473 U.S. 667, 678 (1985)); see also United States. v. Hamilton, 107 F.3d 499, 509 (7th Cir.), cert. denied, 117 S. Ct. 2528 (1997); Gonzalez, 93 F.3d at 316; United States v. Maloney, 71 F.3d 645, 653 (7th Cir. 1995), cert. denied, 117 S. Ct. 295 (1996) (each reiterating that evidence is material if its suppression undermines confidence in the outcome of the trial).

The Government's Arguments Based on the Four-Part Test

Relying on cases decided under Rule 33, the government argues that defendants' motion fails each part of the four-part test required under that rule. As noted above, Brady, rather than Rule 33, provides the requirements defendants must meet, and this makes a difference which is immediately apparent. The government initially argues that because the defendants knew prior to trial that their competitors had submitted stability data to the FDA, they fail the first part of the Rule 33 test. The government contends that it is not what the data shows, but rather that the data had been submitted to the FDA, which is important for Rule 33 purposes.

We would not be persuaded by this argument even if Rule 33 provided the governing test, because we think the relevant fact is not that the stability data had been submitted to the FDA, but that the data contained information indicating that Lactulose with a pH level as low as 2.5 was entirely stable and effective. But Brady, not Rule 33, applies to the situation, and the government's argument clearly does not fit a Brady analysis. As we shall see, the stability data in the possession of the government threw substantial doubt on its theory of the case and was therefore evidence favorable to the defense. The fact that the defendants knew stability data had been submitted to the government, without knowing what it showed -- and without any easy means of obtaining this proprietary information -- is irrelevant. There is no suggestion that the defendants knew or even had any reason to suspect prior to trial that the stability records contained information favorable to them.

Next, the government argues that the defendants failed to use due diligence to discover the stability information prior to trial. This second part of the Rule 33 test is not part of a Brady analysis, so it need not detain us long. The government sees no reason why the defendants did not seek the stability information from the competitors or from the FDA prior to trial, even though they had no way of knowing the effort would produce evidence favorable to them. It would not have been a simple matter, nor can the court say at this time how it would have ruled had discovery motions been made. It is likely the competitors would have objected on the basis of the proprietary nature of the information, and the court probably would have applied a balancing test. This could have resulted in a finding that the probability of favorable evidence was too speculative to justify the intrusion. As far as the FDA itself is concerned, the government strenuously objected to the defendants' motion to produce the stability records even after the U.S.P. disclosure of what the records showed and the present motion had been filed by the defendants. The government argued that the work involved in locating and producing the records would be an enormous and unnecessary burden.

Even if the Rule 33 "due diligence" test applied, therefore, we believe it would not require the defendants to have undertaken pretrial discovery motions to obtain the competitors' stability data. It is by no means clear that, had they done so, they would have been successful.

In any event, the government cannot reasonably argue that defendants failed to do anything they needed to do in order to satisfy Brady. They moved repeatedly for production of Brady materials and both they and the court were assured by the government that all such materials would be produced, both those that were "exculpatory," and those which were "favorable" to the defense.[13] The defendants had a right to rely upon the government's obligation to produce favorable evidence even without such an assurance, but certainly with the assurance it was reasonable for the defendants to believe that no favorable evidence was being withheld.

---

[13] See p. [14a], supra.

The third part of the test under Rule 33 is that the newly discovered evidence must be "material and not merely impeaching or cumulative." The government has a variety of arguments as to why the stability data would have been irrelevant, confusing, and generally inadmissible. It contends, for one thing, that the evidence would have resulted in 'mini-trials' concerning the comparability of the various competitors' manufacturing processes and testing methods to those of ALRA to determine whether the competitors' results supporting the 2.5 pH level would be indicative of the safety of ALRA's Lactulose at the same level. In a curious begging of the question, the government argues that a major distinguishing feature of ALRA's Lactulose is that it had been injected with sodium hydroxide, as alleged in Counts 3, 4 and 6.

This kind of argument puts the burden in the wrong place. It could be that the competitors' stability data would ultimately prove unpersuasive to the jury, or even turn out to be inadmissible. But there is no reason at this point to think that either of these things would be true. The government's case was presented without any suggestion that the various standards to which it sought to hold the defendants were not supported by relatively uniform manufacturing processes and testing methods throughout the industry. For the government now to suggest that the pH range shown to be safe for the rest of the industry is inapplicable to ALRA is a new position for which it has no evidence. The stability data is apparently favorable and certainly bears on a material issue. It is not cumulative of any other evidence, but instead contradicts the evidence in the case concerning the low end of the safe pH range for Lactulose.

The fourth part of the Rule 33 test is that the newly discovered evidence would "probably lead to an acquittal in the event of a new trial." How probable the acquittal must appear is not altogether clear under the cases, but that question need not be resolved because the test is different, or at least differently phrased, under Brady, and that is the test we will apply.

THE BRADY ANALYSIS

We now turn to the parties' arguments under Brady. The tests, it will be recalled, are that (1) the prosecution suppressed evidence; (2) the evidence was favorable to the defense; and (3) the evidence was material to an issue at trial.

Whether the Prosecution Suppressed Evidence

The government argues that it did not "suppress" favorable evidence because it did not know of the U.S.P. recommendation for a change in the pH range until after trial and, secondly, the defense could have obtained the stability data in the exercise of due diligence prior to trial.

There is some sleight of hand in the government's position. The primary favorable evidence is not the U.S.P. recommendation made in June of 1996, four months after the trial. The recommendation would probably be admissible at a new trial, and would undoubtedly be favorable to the defense. But the fact that the recommendation had not been made prior to the trial is irrelevant to the present motion. The favorable evidence that was suppressed is the stability data that was in the possession of the government for years prior to trial, which it does not deny it knew about and which it did not disclose to the defense. The failure to disclose this data satisfies the suppression requirement.

The second part of the government's argument concerning the suppression requirement switches to the stability data itself, rather than the U.S.P. recommendation or the competitors' application which prompted the recommendation, and suggests that the defendants could have obtained the data prior to trial. As we have already indicated in the discussion of Rule 33, it is not clear the court would have ordered pretrial production of the data. But we need not decide that question in order to do the analysis under Brady, which imposes an affirmative obligation on the government to produce favorable evidence. United States v. Gonzalez, 93 F.3d 311, 315 (7th Cir. 1996); United States v. Payne, 102 F.3d 289, 293 (7th Cir. 1996). The government expressly recognized its obligation to do just that and the defendants were justified in relying on that assurance.

The first requirement under Brady, that the prosecution suppressed evidence, has been satisfied.

The second and third Brady requirements are that the evidence was favorable to the defense and that it was material to an issue at trial. The last requirement comes down to whether the government's suppression of the evidence "undermines confidence in the outcome of the trial." Payne, 102 F.3d at 293.

In this case, the question of whether the stability data was favorable to the defense and the question of whether its suppression undermines confidence in the outcome of the trial are closely related and it will be convenient to discuss them together. The court answers both questions in the affirmative, for the following reasons.

There is no reason to doubt that the stability data showing the safety and therapeutic effectiveness of Lactulose at a pH level as low as 2.5 would had been admissible at trial. The government offered evidence of the 3.0 - 7.0 range, and certainly any data from the same manufacturers tending to support a lower range was relevant. In fact, had the stability data been made available, it is likely the government's presentation on the "dangerousness" issue, if made at all, would have been quite different than it was.

The government argues that a 2.5 level would have had nothing to do with the evidence in the case because there was no contention that the Lactulose involved in Counts 3, 4, and 6 ever dipped to a pH level that low. The test records of ALRA showed that the Lactulose in question at the time sodium hydroxide was allegedly injected into the bottles was approximately 4.6.

However, it was the government's contention that at the time of the injections the Lactulose had degraded to a point where, had its true pH been tested and determined by the purchasers, they would have learned that the product had degraded so far that it was or would soon be unfit for use. This explained the defendants' need to distort the true pH by adding sodium hydroxide that would elevate the pH reading and mask the decomposition of the product. This was the prosecutors' theme from the beginning to the end of the trial: to avoid losing profits on these decomposed Lactulose lots, the defendants manipulated their pH levels in order to make them appear saleable.

The court does not recall that the government conceded in its argument to the jury that ALRA's records as to the actual pH of the product prior to the alleged injection were accurate.[14]

In fact, it was a major contention of the government throughout the trial that ALRA's records were, generally speaking, unreliable.[15] But more than that, the government repeatedly emphasized that the naturally occurring process of degradation was continuous, so that even if the actual pH level was at 4.6 when the injections occurred, the jury still could have concluded that the defendants recognized the need for a "booster" before distribution in order to avoid detection of a real problem that would appear shortly after distribution. Had the jury known that, according to stability data from the very manufacturers whose records had been used to support the recommended range of 3.0 to 7.0, the level of 2.5 was shown

---

[14] Indeed, in one of its briefs filed in opposition to the present motion, on October 2, 1996, the government made this point:

> Second, based on the trial testimony of several witnesses, the laboratory testing conducted for and reported by theDefendants was not reliable.... Accordingly, the fact that ALRA's pH test results for lots 52-230-P and 52-231-P were recorded as being within its specification was neither surprising nor probative

Government's Memorandum on the Question of Whether the Jury was Misled in Regard to the Matter of Lactulose Degradation, p. 24.

[15] If the court recalls correctly, Rule 404(b) "other acts" evidence was admitted, over defendants' objection, to support the government's contention that much of what the defendants did in the operation of their business could not be accepted at face value.

> not to have any significant impact on the safety and quality of this product: it does not in any way affect the laxative properties of the product, and it does not affect the level of the related substances[16]

the jury could well have reached a different conclusion as to whether the defendants had a motive to jiggle the pH of their product. The level of 4.6 is not in the danger zone, and according to the competitors' stability data, the level of 2.5 was not in the danger zone. It is this fact -- that no problems of any kind had been reported at a 2.5 level -- that would have cast serious doubt on the government's motive theory. And, if the defendants had no motive to order their employees to engage in the cumbersome process of injecting sodium hydroxide into the Lactulose bottles, it is difficult to understand why they would have done it. The government obviously recognized how essential it was to prove a motive for behavior which, absent a plausible motive, would be inexplicable.

In short, the lower the safe pH level, the less reason the defendants would have had to be nervous about a level of 4.6 or anything in that area, and the less motive they would have had to do what is charged in Counts 3, 4, and 6.

Moreover, the testimony of Dr. Senior concerning the dire consequences of ineffective Lactulose would have had no purpose if the government was not contending that the Lactulose in question was dangerous. Nor would the emphasis on that testimony in the prosecutor's opening statement and closing argument have made any sense if the government was not arguing that the Lactulose was in fact dangerous.

---

[16] U.S.P. bulletin of June 1996 quoted in full at p. [16a] supra.

The government attempts to avoid the consequence of its emphasis on the dangerousness of the Lactulose by pointing out that its argument to the jury was based in part on testimony that the injection of sodium hydroxide by itself rendered the product dangerous. This is another question-begging argument; it assumes the defendants did inject the Lactulose. We are concerned on this motion with the suppression of evidence that went to the question of whether they did so.

There is another respect in which the stability data is material, quite aside from the question of motive. The evidence at trial was that testing of the lots in question had shown the pH level of the Lactulose to have increased for no apparent reason after the date of the alleged injections. The government's expert witness, Dr. Hicks, testified that the only explanation for this occurring in a closed container would be the addition of a base, such as sodium hydroxide. The defense expert, Dr. John Robyt, disagreed and said that the variations could be due to laboratory error. The government relied heavily on the testimony of Dr. Hicks in its final argument to the jury.

The competitors' stability data shows some variations in pH -- going up, back down and then up again - that are arguably similar to those shown in the ALRA records for the lots in question. The government argues that the increases in pH shown in the competitors' stability data are significantly lesser increases than those shown in the ALRA test data. Whether this is true or not is a somewhat complicated factual question, and one properly for the jury.[17] But even if it were true, it detracts little, if at all, from the materiality of the competitors' test data. Dr. Hicks testified that no increase could occur in a closed container without tampering. If the competitors' data show that any increases occurred in their laboratories, the data appears to contradict Dr. Hicks on this important question. Had the competitors' data been available to the jury, the defendants would have had support for their position that any unexplained variation in their own test results could have been due to laboratory error. There may be other or better arguments the defendants could have made.

---

[17] In its effort to distinguish the competitors' data, the government offers considerable factual information and analysis that is found neither in the data itself nor in the trial record.

The government argues that the evidence of the defendants guilt on Counts 3, 4 and 6 was so overwhelming that the competitors' stability data would have made no difference to the jury. This is not how the court remembers it. The description of the injection process given by the various employees' who allegedly did it seemed unlikely in the extreme, unless there was some compelling motive for the defendants to have required them to engage in such a procedure. Not all of the employees who would have known about the incident agreed that it had occurred. Both of the Bhutanis denied that it had occurred. It seemed to the court at the time that the verdict could have gone either way, and, of course, there is no way of knowing how close the jury thought the question was. One thing that can be said for certain is that if the jury had entertained a reasonable doubt as to whether the defendants had a plausible motive for engaging in what otherwise would have been bizarre behavior, it could not have found the defendants guilty on Counts 3, 4 and 6.

The government's suppression of the evidence concerning the competitors' stability data seriously undermines the court's confidence in the verdict of the jury on Counts 3, 4 and 6. The court concludes that the defendants have satisfied the requirements of Brady v. Maryland and are entitled to a new trial on these counts.

The Spillover Question

The question remains whether the suppression of evidence specifically relating to Counts 3, 4 and 6 undermines confidence in jury's verdict on the other counts of conviction. The defendants argue that it does, inasmuch as the jury must have been affected in their consideration of the other counts by their finding that the defendants, motivated by a desire for profit, sold defective Lactulose that would be used by unsuspecting patients for whom it would pose a risk of serious injury or death. The remaining counts of the indictment all charged the same kind of shoddy, unscrupulous behavior, motivated by desire for profit and indifference to public health. The government's description of these counts, and its explanation of why there was no prejudice that could have spilled over on to them, is wholly unpersuasive. Indeed, merely quoting the government's argument exposes the close connection among all the counts on which defendants were convicted and the consequent likelihood of a spillover effect:

> Moreover, the absence of competitors' stability data could have had no 'spill-over' effect on the other counts of conviction unrelated to Lactulose stability (i.e. counts relating to the leaking Lactulose Drums, the K+10 contaminated with a metal pipe, and the HITS training program, and the conspiracy which includes various recordkeeping deficiencies), as the jury found ample evidence on those counts.
>
> Finally, contrary to Defendants' claim, the jury's verdict was in no way tainted by the Government's theme (articulated in its opening statement and closing argument) that ALRA's modus operandi was to sacrifice

> the public health to make a profit. This theme was clearly borne out by the evidence relevant to the counts of conviction: selling Lactulose adulterated with sodium hydroxide injections (i.e., Count Three, Four, and Six); selling Lactulose from leaking drums (i.e., Counts Seven and Eight); selling K+10 with fragments of metal pipes ground up in it (i.e., Count Ten); and failing to employ trained technicians in manufacturing human pharmaceuticals (i.e., Count Fifteen).[18]

The court agrees with the defendants. All counts of conviction were entwined with the government's profit motive theory and its contention that the defendants would cut any corners they had to regardless of the consequences to public health. A finding that the defendants were so motivated could well have provided the basis for the jurys verdict on the other charges, each of which was vigorously contested. It is true that the defendants were found not guilty on some counts and that the jury failed to reach a verdict on others. Any effort to reconcile the different results would be entirely speculative, and it is impossible to conclude from those results that the Brady violation had nothing to do with the jury's conclusion on any count where guilt was found. The court has the same lack of confidence in the verdict on those counts as it does on Counts 3, 4 and 6.

---

[18] Government's Opposition to Defendants' Post-Trial Motion for a New Trial Based on Newly Discovered Lactulose Stability Evidence, filed June 16, 1997, pp. 39-40.

CONCLUSION

Because of the government's violation of Brady v. Maryland, each of the defendants is granted a new trial on each count of conviction.

DATED: December 16, 1997

ENTER: ______________________________

John F. Grady, United States District Judge

[**5866**] (The following proceedings were had in open Court outside the presence and hearing of the jury:)

MR. MEAD: Your Honor, a few proposals on the jury instructions and a few objections.

First, for the record, I object to the Court's failure to give Alra request number ten submitted to the Court; to the deletion of the sentence with respect to the defendant's theory of the case on count thirteen with respect to the fact that underlying data - the failure to provide the supporting data should be, at least by the jury, to with respect to Dr. Bhutani's intent as well as the materiality. You have already ruled on that also.

I want to preserve our objection to your failure to grant Alra request No. 12, which is the request for a materiality requirement on the failure to maintain records charges on that prong of the conspiracy count.

I also, your Honor, noticed with respects to count three and count six of the indictment, which charge adulteration of the Lactulose lots where the allegation is with respect to the addition of sodium hydroxide, there are three prongs charged with adulteration. And I noticed, as you were reading them, that the last prong, which is a violation of good manufacturing practices, fails to specify in what manner the lots had violated GMP. It is my understanding that the government's allegation with respect to the violation of [**5867**] six borrows from that same definition, so if we were just to tell them.

THE COURT: What page is six?

MR. MEAD: Page - six is page 53, but we don't repeat the long definition of adulteration because you had previously defined it in count three and they are essentially the same in terms of the definition of adulteration.

MR. MCDADE: Your Honor –

THE COURT: Yes.

MR. MCDADE: I mean, number one, if the objections were going to be made, it should have been made prior to the time that the jury was instructed. The instruction states the requirements set forth in good manufacturing practices regulation include requirements concerning the use of appropriate raw materials, the requirements of master control records be maintained and followed in the manufacture of the drug product.

I think that in the context of the evidence, the instruction is – is adequate. The nature of the GMP failure to follow was: One, they used a procedure that wasn't specified in the ANDA. Secondly, that they didn't document the procedure that was used.

THE COURT: I think you're right. I think it's reasonably clear what the instruction means. The fact that none of us noticed that alleged defect before now I think is [**5868**] evidence of that. So I'll refuse to give any supplemental instructions on those counts.

MR. MEAD: Your Honor, with respect to counts seven and eight, I realized, as you were reading the instructions that the way – the way the government drafted these counts, I was basically following as you read the summary of the indictment. I realized that the way the government drafted these counts is the contamination occurred after Alra got [...] stuff. That's what the indictment says, and I would like to request an instruction that says, the reasonable possibility of contamination had to occur after the product reached Alra warehouse because that's the way the government charged in the indictment.

The government introduced evidence to a different effect talked about in-transit, and that's why I think it's important that that clarification be made in terms of what's charged in the indictment.

MR. MCDADE: And, your Honor, that is not the government's position. The government's position is that the use of product that had been held - drug components that have been held under insanitary condition is what constituted the three - 3(k) charge.

THE COURT: I am going to refuse that addition as well.

MR. MEAD: Your Honor, with respect to count ten, I [**5869**] [...] intent was that the good faith instruction would relate to [...] of the counts in the indictment because they all required intentional misconduct.

MR. TUITE: That's on page 72, Judge, and my suggestion would be it be placed after page 81.

THE COURT: Page -

MR. TUITE: Right now it's page 72. Before if you find beyond a reasonable doubt, then you find them guilty. If you don't, not guilty. So it should either be before that or after that. Then it would apply to all of the counts as 81, page 81, court instruction 31.

THE COURT: No. I don't want anything coming after 80.

I should say, by the way, that what we say in the good faith instruction is simply a repetition of what I say repeatedly in the previous portions of the instructions when I tell the jury about intent, knowledge -

MR. MCDADE: Your Honor, the government would request that the instructions remain in the order as they were given. I would suggest that, at this point in time, the jury was taking notes on the instructions; that -

THE COURT: That's what I'm going to do. I am going to leave them in the order that they are. All right.

MR. KOWAL: Judge, are we doing - should I make a record of the instructions that we refuse at this time?

[**5870**] THE COURT: Yes. But the jury wants to go to lunch, so I am going to let them go to lunch.

MS. SMOLOVER: These are 12 copies of the jury instructions without any citations on the bottom.

THE COURT: Good. Good. Now verdict forms.

MS. SMOLOVER: Your Honor, as well, there are three different piles of the verdict forms each with respect to each of the defendants.

MR. TUITE: You only need three. You don't need 12.

THE COURT: No. I am going to send copies in for them to use as -

MR. BRANDING: - working copies.

THE COURT: - working copies, right. But make sure we have about 14 instead of just 12.

MR. TUITE: You got 14 of them there?

MS. SMOLOVER: Yes.

THE COURT: I think that will to do it. Okay. Take them to the jury, and then the jury is ready to go to lunch. They are going to eat on the second floor by the way.

MS. SMOLOVER: Your Honor, can I state one typographical error that I noticed, so it's on the record.

On page 68 of the instructions there, the last line, and this is with respect again to count thirteen, false statements. It reads, GMP methods for testing Valproic Acids here preservation USP; it should be preservatives USP.

[**5871**] THE COURT: This is page 68. Oh, I see preservation. They'll understand that because it's in the instruction twice earlier.

Do you have, Ms. Smolover, another set with the markings, with the numbers on them?

MS. SMOLOVER: Yes, your Honor.

THE COURT: Thank you. And then a set of the verdict forms for me, too.

MS. SMOLOVER: There should be a difference in pagination of one page between the ones with the citation and ones without citations because the citations move the pages over.

THE COURT: Thank you. Okay. Go ahead, Mr. Tuite.

MR. TUITE: Judge, we were doing some housekeeping on exhibits. We were –

THE COURT: Will you give me just a couple minutes? I will be right back out.

(Brief pause.)

MR. TUITE: Judge, we had not formally moved, although we have shown the witness in his testimony Defendant Exhibit 7, which is the 1996 registration; defendant's 9, which was his guidelines for dealing with the FDA; Defendant's 73, which I think was already in the ANDA but it's the letter that he wrote in May of 1988 concerning stability studies concerning the Lactulose.

[**5872**] Defendant's Exhibit – we are not offering 59A which was a memo or 172, which was Dr. Mitchell's handwritten notes for lack of foundation.

The letter B23, which was the letter from Joel Davis saying they were in compliance and the letter B26, which was a letter from Dr. Molecko of November 8, '91, saying you can resume operations. B27, the letter from Mr. Molecko in '92 saying they were in substantial compliance.

We are not offering the Searle documents that only had to do with the issue of overfilling, but that's really not an issue.

The stickers, the five stickers – the six stickers that we showed Dr. Bhutani showed as a demonstrative piece of evidence, the type of stickers that are used for various stages of production. And photos 8, 9, 10, 11, 12, 13, the calibration documents, the sheet with the names of the people training one and the names of the people who participated in training with this note to Mr. Simpson. And Valproic Acid documents 1, 2, and 3. One being his notes of the November 9, meeting; two being the March Lynch memo of February 1993. And three, being the March 26th FDA memo of John Harris, which has already been testified about. Those are the ones we move.

THE COURT: All right.

MR. MCDADE: Your Honor, it was my understanding that unless they were objected to and sustained that they were in.

[**5873*] MR. TUITE: Okay. It's also 145, 147 and 146, which are in without objection.

THE COURT: Now, are the government's in that basket?

MR. MCDADE: Yes, your Honor.

MR. TUITE: We haven't seen everything here. We thought would just check with each other.

THE COURT: Go over what's there. Otherwise, I will assume it's okay and have it in there by the time they get back they.

MR. TUITE: If they want to watch the video, they don't have to, then they have to request equipment.

THE COURT: I'd like you to remain reasonably near because they may have some questions, and I don't want to take a half hour to assemble everybody.

MR. MCDADE: The only remaining –

THE COURT: I think you can figure it's – let the record show they went out at 1:00 o'clock, and it's 1:20, so you are certainly free until 2:00 o'clock.

MR. MCDADE: Your Honor, the only remaining issue that I am aware of there was a discussion during the charging conference with regard to lesser included offenses and the defendants specifically indicated they did not want an instruction on lesser included offenses.

MR. TUITE: Right. And that is true, Judge. We have [**5874**] talked to both Dr. Bhutani and Mrs. Bhutani, and neither one wishes lesser included offenses submitted to the jury.

MR. MCDADE: And that's also for Alra Laboratories as well?

MR. MEAD: That's correct. Alra does not request lesser included offenses.

MR. KOWAL: Just briefly, for the record.

THE COURT: Do you agree that Neelam Bhutani does not want lesser included offense instructions?

MR. KOWAL: Yes. There were just four of the instructions that I had submitted, Judge, that I wanted to make a record on.

Neelam Bhutani proposed instruction number 12 dealt with the effect of violation of FDA regulations saying that, in essence, a violation of the regulations was not a criminal offense. I had offered that in chambers and your Honor refused that.

Neelam Bhutani proposed instruction 13 was an interpretation of good manufacturing practice regulations, which basically said that if there was any ambiguity, the defendants could turn to the industry documents or exercise good scientific judgment.

THE COURT: I refused that, by the way, because it didn't seem to me that there was any evidence of any ambiguity that in fact had been the source of a reference to some [**5875**] outside material like a guidebook or anything of that kind.

MR. KOWAL: We had - I guess, I had focused on it from the standpoint of Mrs. Bhutani because of the exercise of scientific judgment in dealing with test results and the nature of the laboratory and that was the subject of Mr. Lord's testimony.

THE COURT: I think that that is simply subsumed under the numerous instructions under fraudulent intent.

MR. KOWAL: The next one, your Honor, was proposed instruction 16, which was our description of FDA's inspectional authority to compel interviews during its inspections.

THE COURT: I refused that this morning because it seemed to me that that was not an issue that I had not covered during the trial, and it's not involved in any of the charges, so I saw no need to include it.

MR. KOWAL: And the last, your Honor, I'd like to make a record on is proposed instruction 22; the theory of defense instruction by Neelam Bhutani, which I submit to the Court, was a instruction which was submitted by the evidence and incorporated her theory of defense in each count.

THE COURT: As far as theory of defense is concerned, I think that all three defendants' theories of defense are amply covered by the instructions that the Court gave, even though that magic phrase "theory of defense" is not used.

[**5876**] I have often thought incidentally that if I were a defense lawyer, I wouldn't want my defense referred to as a theory. Theory has sort of a second-class representation I think in common parlance. Anything else?

MR. KOWAL: I have nothing further, your Honor.

MR. MEAD: Your Honor, on behalf of defendant Alra Laboratories, I want to formally join the request for codefendants for jury instructions and repeat my understanding that throughout the course of the trial objections by one defendant have been adopted by the others.

THE COURT: That's correct.

Now, it's - I don't know whether this jury intends to knock off at 5:15 or not according to their usual pattern, but I intend to knock off. I am going to - I have an engagement this evening, and I can stay here until 5:45 but not after.

So I didn't want to say anything to the jury until it was necessary, but if you have not heard anything from me or Alyce before, say, 5:00 o'clock, will everybody please be back here at 5:00 o'clock because then I will call them out and see what their pleasure is. If they say they want to leave at 5:30, I will instruct them to come back tomorrow morning.

If they say they want to continue deliberating, what I would be inclined to do would be to allow them to do so in my absence, but if that they should reach a verdict this [**5877**] evening, return tomorrow morning for the purpose of delivering it. And I think I would even tell them not to fill it out, so we don't have any problem about the custody of the verdict form overnight.

But think about that in the in the meantime –

MR. MCDADE: Yes, sir.

THE COURT: – and we will talk about it.

MS. SMOLOVER: We will be filing the government's proposed instructions in the clerk's office with the citations. Is it also our responsibility to file the jury instructions themselves – actually a copy that went to the jury?

THE COURT: No. No. No. Those just go in the waste – the paper disposal at the end of the trial.

MS. SMOLOVER: Okay.

THE COURT: But if you will just file with the clerk – you can give it to Alyce for that matter – our numbered set.

MR. MCDADE: Yes, your Honor.

MS. SMOLOVER: Okay.

MR. TUITE: Judge, I think I speak for all of us that thank you for a very nice trial. For this long a trial with this many documents and not an exciting case, I really appreciate the way you handled it.

THE COURT: Well, thank you.

[**5878**] MR. TUITE: We like being here.

THE COURT: I think all of you represented your clients very well. And in terms of the length of the trial, as we said yesterday, it came out just about what we told them it would, and I think maybe I have been too apologetic to the jury during the course of this thing.

I was quite concerned about the possibility of losing somebody and having the prospect of a mistrial, but thank goodness that's behind us.

MR. BRANDING: Just for your information, there was an accounting done this morning or last night. By the defendant's calculation there were 58 witnesses; both sides total that testified.

THE COURT: I keep a tab myself, and I had 57. Some of them were repeaters.

MR. BRANDING: That's too close to dispute.

THE COURT: A lot of witnesses and a lot of evidence.

Okay. Well good luck to everybody.

MS. SMOLOVER: Thank you, Judge.

MR. MEAD: Thank you, Judge. It's been a pleasure.

(The trial was adjourned at 1:45 until 5:00 p.m. of this same day and date.)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,)
Plaintiff,)
) No. 93 CR 585
-vs-)
) Chicago, Illinois
BALDEV RAJ BHUTANI, et al.) January 24, 2000
Defendants.) 10:00 o'clock a.m.

REPORT OF PROCEEDINGS - Sentencing
BEFORE THE HONORABLE JOHN F. GRADY

For the Plaintiff:	MR. LAWRENCE McDADE U. S. Department of Justice Office of Consumer Litigation 1331 Pennsylvania Avenue, NW Washington, D.C. 20004
For the Defendants:	MR. PATRICK A. TUITE (Arnstein & Lehr) 120 South Riverside Plaza Chicago, Illinois 60606-3910 (312) 876-7877
	MR. CHRISTOPHER MEAD (London & Mead) 1225 - 19th Street N.W. Washington, D.C. 20036
Official Court Reporter:	Geraldine D. Monahan 219 South Dearborn Street Room 1928 Chicago, Illinois 60604 (312) 435-6890

[**38**] THE COURT: I said I would come back to that. I certainly want to do it. I thought we were going to come back to it --

MR. McDADE: That's fine.

THE COURT: -- when we decide whether that's a separate amount that we consider somehow separately or whether it gets folded into the whole case.

MR. McDADE: And then the other, your Honor, is just for the record, it is noted in the PSI, the government had suggested that the investigative costs were also an appropriate measure of loss. The defense objected, and Probation agreed with the defense on that point.

THE COURT: And I agree with the probation officer. I don't think there is any warrant at all for including investigative costs. I think that's overreaching by the government. There would just be no controlling that, and I don't think that that's an appropriate guideline item, so that will be denied.

Now we come down to line 209 on page 9 and reach the question of whether the offenses involved the conscious or reckless risk of serious bodily injury, pursuant to Guideline 2F1.1 (6).

This is a very different question than whether the customers got what they paid for. The latter question goes to the amount of the customer's loss, but this question under 2F1.1 [**39**] is something entirely different. It involves, first of all, a state of mind on the part of the defendant that is conscious or reckless. Negligence doesn't qualify. It has to be conscious, meaning intentional, for practical purposes, or reckless, which means having a conscious disregard for the safety of others.

And it has to be the conscious or reckless creation of a risk of serious bodily injury, and there simply isn't the least bit of evidence from which the Court could conclude that that guideline has been met in this case.

Taking the counts one by one, there is no evidence that Dr. Bhutani regarded the injection of Lactulose into the individual bottles with syringes as creating a risk of serious bodily harm to people who might use the Lactulose syrup. What was being injected was sodium hydroxide, which was something that was normally added to the drug. What occurred here was that it was added in a different manner than authorized by the regulations, and the addition in that manner was not documented.

There is no evidence that Dr. Bhutani thought that the addition of the substance in the manner it was added or the failure to document it created any risk of any serious injury to anybody.

The government had itself changed its position as to what the risk was at least three times during the course of this litigation. It told the jury at trial that the risk was in the [**40**] Lactulose itself in that it had degraded or decomposed to the point where it was no longer medically effective and that the injections of the sodium hydroxide were made to mask or conceal that fact. There was very little emphasis in the trial on any danger from the injection itself, let alone any emphasis on the proposition that Dr. Bhutani should have known that he was creating a risk of serious injury by adding the sodium hydroxide.

When the case went up on appeal, the government took a different position, and now when we are back here for sentencing, the government seems to be taking still a third position, that is, that the injection of Lactulose into the bottles would not have resulted in its even distribution without the bottle but instead would have formed globs or pockets of sodium hydroxide which could have had a deleterious effect upon the user. And there apparently is some testimony that received very little emphasis during the trial that would tend to support that possibility, but there is no evidence that Dr. Bhutani knew that or was conscious of it or recklessly disregarded the possibility.

So, as to Counts 2, 4 and 6, this element simply does not apply. It applies no more to Counts 7 and 8. There is no evidence whatever that the Lactulose that was used from the leaking drums had anything medically dangerous about it or that it would cause anybody any injury. There was no evidence of any [**41**] actual contamination. The jury found the defendants guilty on the proposition that the reasonable possibility of contamination would be sufficient, but the reasonable possibility of contamination and the risk of serious physical injury are two very different things.

People eat contaminated food every day of their lives. There is nobody in this room who won't eat some before the day is out. Our bodies are amazingly capable of warding off ill effects from contamination. And there is no evidence at all in this record that anything about these leaking drums was in fact dangerous to anybody. And there certainly is no evidence that Dr. Bhutani was conscious of or in reckless disregard of a risk of serious injury from the leakage of the drums or any possible contamination associated with that leakage.

Now we come to the K+10 tablets. There is no evidence that anyone was likely to be hurt from these tiny metal fragments that were in some of the pills. As the government concedes, we don't know how small the fragments were. They were certainly tiny. And there is no evidence that they presented a risk of serious, and I understand score the word "serious" bodily injury, or that

Dr. Bhutani was conscious of such a serious risk. So there will be no enhancement for conscious or reckless risk of serious bodily injury under any count of the indictment.

Now, we come to page 10 and address adjustments for [**42**] role in the offense. The probation officer concludes that the defendant was an organizer or leader of this criminal activity involved in these counts. And since he was the person who was in charge of the plant and who had overall supervision of the operation and indeed was shown by the evidence to have directed the various activities involved in these particular offenses, I think it is correct that the defendant should be considered an organizer or leader of the criminal activity, and --

MR. TUITE: May I just address that for one second?

THE COURT: Yes.

MR. TUITE: While he is the, was the president of the corporation, to go from two points to four points requires a finding that this criminal activity either had five people who were criminally responsible and there wasn't, or that the operation was otherwise extensive. And unless you're making a finding that it was extensive, my reading of your finding of --

THE COURT: I really meant to an address that.

MR. TUITE: -- three isolated incidents over the years, and so we are objecting that it's otherwise extensive.

THE COURT: I think that the otherwise extensive doesn't have to mean the activity, it can mean the number of people involved in it, whether or not they were knowing participants. And I think there were a lot of unknowing participants in the offenses involved in Counts 2, 4 and 6 that would qualify this as otherwise extensive.

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF)
AMERICA,)
Plaintiff,) No. 93 CR 585
) Chicago, Illinois
v.) February 15, 2000
) 10:30 a.m. and 2:00 p.m.
BALDEV RAJ BHUTANI,) Sentencing Hearing
NEELAM BHUTANI)
and ALRA LABORATORIES,)
Defendants.)

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE JOHN F. GRADY

APPEARANCES:

For the Government:
UNITED STATES
DEPARTMENT OF JUSTICE
OFFICE OF CONSUMER LITIGATION, by
MR. LAWRENCE G. MC DADE
Deputy Director
1331 Pennsylvania Avenue, N.W.
Suite 950 North Washington, D.C. 20004

For Baldev Raj Bhutani and Alra Laboratories:
ARNSTEIN & LEHR, by
MR. PATRICK A. TUITE
120 South Riverside Plaza
12th Floor
Chicago, Illinois 60606

For Neelam Bhutani:
LONDON & MEAD, by
MR. CHRISTOPHER B. MEAD
1225 19th Street N.W.
7th Floor
Washington, D.C. 20036

Valarie M. Harris - Official Court Reporter
219 South Dearborn Street - Room 1902
Chicago, Illinois 60604
(312) 435-6891

[**120**] information they've provided is accurate.

THE COURT: I think so. Whatever is customarily provided.

MS. EHRLICH: I don't know what that is, but --

THE COURT: I don't either, but whatever is necessary to give the best assurance that we can get that the information is accurate ought to be provided.

And let me say I have no objection to counsel for the parties working with Ms. Ehrlich or whoever is designated by the probation office to do this, because I think it's going to have to be a cooperative effort. It's a very complicated inquiry.

All right. Then that's it for the corporation for the time being. Now let's get back, then, to the question of bond on appeal for Dr. Bhutani.

MR. TUITE: Thank you, Judge.

We filed, Judge, a motion and a memorandum in support.

THE COURT: Yes, I've read that and the government's response.

Maybe I can help you here by telling you what my reaction is.

Let me give you back, Mr. McDade, your Title 18 book here.

MR. MC DADE: Thank you, Your Honor.

THE COURT: The defendants' memorandum suggests a [**121**] large number of issues that Dr. Bhutani intends to raise on appeal that it -- that he argues to me are close questions. I'm not going to talk about all of them because it's unnecessary. I'm just going to talk about some of them. And the ones I want to talk about start at page 4 of the defendants' memorandum at the very top there.

There is a very substantial issue as to whether the defendants were deprived of a fair trial by the evidence and the arguments of the government to the effect that the lactulose they were selling to the public was dangerous, that it was medically ineffective and dangerous.

Now, the government took the position after the trial that it didn't argue that and that it didn't submit evidence to that effect, and it persuaded the Court of Appeals on the Brady phase of the case, B-r-a-d-y, that indeed it had not submitted such evidence or made such arguments.

I don't know what the defendants' prospects are of getting the attention of the Court of Appeals again on that question. I am convinced that if the defendants do get the attention of the Court of Appeals, there is a good likelihood that a new trial will result, and that is because the jury was led to believe that the defendants were selling drugs that were dangerous and life-threatening, even life-threatening to children.

And as I said on more than one occasion, the most [**122**] dramatic evidence in the case was that of Dr. Senior that was precisely to that effect. There is no doubt whatever in my mind that this jury thought these defendants were guilty of selling drugs that were dangerous because they had decomposed to the point that they were either ineffective or dangerously close to being ineffective.

The analysis on appeal bond is whether the defendants raise a substantial question, and that question that they intend to raise is substantial. Indeed, as I've indicated, I think that it is so substantial as to hold the great promise that they will win a new trial if they can get the Court of Appeals to consider it.

But once the defendants have raised the substantial question or show the intention of raising a substantial question, then the trial court must assume that the substantial question will go the other way on appeal. This is the language that the Seventh Circuit quoted from another case when it discussed the kind of analysis that the trial judge should engage in, in the case of United States against Bilanzich, B-i-l-a-n-z-i-c-h, 771 Federal 2d 292, at page 292, and the case they were quoting from was United States against Powell, 761 Fed 2d at 1234.

So I think that what I'll refer to as the Dr. Senior issue is substantial. And then I am to assume that if it is addressed, it will go adversely to the government. But even if [**123**] I didn't have to assume that, I would assume that becaue the issue is so substantial, that there is a very high likelihood that it will result in a reversal and a new trial.

Now, the second issue that I believe is substantial -- and I don't mean by neglecting to mention the others that are listed in the motion that they are insubstantial, but the second one I specifically identify as substantial is the one about halfway down page 4 about Dr. Bhutani being cross examined on his insurance claim that was the subject of Count 9. Now, I felt very strongly that the defendants could not receive a fair trial on the drug counts if the insurance fraud count were tried along with those counts, and I analyze that in the opinion I wrote granting a severance.

The government urged me to change my mind about that, and in fact I finally grew impatient with Mr. McDade, who just simply wouldn't let it drop. Even up to the very day of trial the government was still attempting to try Count 9 along with the unrelated drug counts. But I made it very clear that I didn't want any reference made to that insurance claim. Yet, when we were I don't know how close to completing the long multi-week trial, sure enough, Mr. McDade asked Dr. Bhutani whether he made a claim for this lactulose in Counts 7 and 8 to the insurance company and received a check from the insurance company, and put Mr. Tuite in the impossible position of either having to object or not.

[**124**] And I can't recall. Did --

MR. TUITE: We objected, Judge.

THE COURT: You objected, and I sustained the objection, but all that really did --

MR. TUITE: I think the defendant answered before.

THE COURT: All that really did was to highlight the incident in the mind of the jury. On the other hand, you really had to object or you'd be deemed to have waived it.

But as the defendant points out in this motion for bail, the jury from that point on knew that Dr. Bhutani, who was asking them to believe him, had made a false and fraudulent insurance claim.

I don't know why Mr. McDade did this when he'd been told not to, except that he was desirous of infusing into the case some prejudicial elements that he thought necessary to survive it from the dreariness that it otherwise had.

This was a paper case, failure to keep records, no showing of any harm to anybody. The government apparently thought from the very outset that it had to excite the interest of the jury in some way and one way was the Dr. Senior type thing, make the jury believe that we're protecting the health of small children here and that the defendants for the purpose of profiting endangered the health of small children.

But that's not all. Let's also let the jury know that Dr. Bhutani was essentially double dipping here. He not only [**125**] put out this contaminated lactulose, but he made a false claim to an insurance company and was paid on the basis of that false claim.

This occurred at a point, as I say, where we had invested weeks and lord only knows how many tens of thousands of dollars into the trial. I don't recall whether a motion for a mistrial was made. If it was, I denied it. And I certainly wasn't going to declare a mistrial sua sponte. I just hoped for the best. But I believed then and believe now that what Mr. McDade did was extremely unfair to the defendant, and it was in direct violation of the orders of this court.

The jury would normally be affected by evidence of that kind, and there is no reason to believe that they were not affected by it in this case. Ironically, should Dr. Bhutani get a new trial, he's now been convicted of that offense, and I suppose that conviction could be used to impeach him should he testify.

The third area that I think justifies the setting of an appeal bond here is at the bottom of page 4 of the defendants' memorandum, and that is that there are so many substantial guideline issues in this case that there is a significant prospect that some of my rulings will be reversed; that is, some of the rulings that went against the defendants will be reversed. And if that occurs, it is certain that the sentence that would be authorized on remand, even if the conviction is [**126**] affirmed, would be less than the time that Dr. Bhutani would have to serve on the 30-month sentence while the appeal is pending.

This is not a case that I would anticipate would be decided quickly. It is simply too complicated. It is going to require a great deal of work on the part of the Court of Appeals. And, accordingly, it will require a great deal of time. And what could well happen here is that unless an appeal bond is set, Dr. Bhutani would run well over the period of imprisonment that would be justified by the guideline rulings that the Court of Appeal might affirm.

This whole question of role in the offense is one of the issues I have in mind. The loss value is a ruling that could easily go the other way in the language of the cases saying what is meant by a substantial question. I see it as the Marcus court saw it, but I can certainly understand how other judges would see it differently.

The question of grouping I think can be argued the other way very reasonably. But if you just take the fraud loss question, what would that result in? The sentence would be cut in half?

MR. TUITE: Exactly.

THE COURT: Exactly in half.

MR. TUITE: It would be a probably 15-month sentence or less.

Important Note:

The Appendix lists all of the attachments to the Petition for Writ of Certiorari.

Attachment L is not available to Petitioner Bhutani at the Federal Prison Camp. Bhutani has written to Mr. Lawrence G. McDade, Prosecutor in this case, asking him to provide these attachments to this Court.

I, Baldev R. Bhutani, respectfully asks this Court to allow Petitioner to amend the Petition and insert attachment L when provided by the United States.

Thank You.

UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BALDEV RAJ BHUTANI **Petitioner-Appellant**	**) Case # 03-1120** **)**
	) On Appeal from the U.S.
v.	**) District Court for the**
	) Northern District of Illinois,
UNITED STATES OF AMERICA	**) Eastern Division** **)**
Respondent-Appellee	**)N.D. Ill. No. 02 C 1817** **)**
	)John F. Grady, District Judge

ENTERED: January 31, 2003

JURISDICTIONAL MEMORANDUM

In direct response to this Court's Order of January 17, 2003, the Government states that Respondent-Appellant, Dr. Baldev Raj Bhutani did not bring a previous petition pursuant to 28 U.S.C. § 2255 challenging the judgment that is the basis for this appeal. Dr. Bhutani's initial Section 2255 Motion (N.D. Ill. Case # 01 C 1121) challenged his conviction and sentence on a mail fraud (insurance fraud) scheme, while the Section 2255 Motion that led to this appeal (N.D. Ill. Case # 02 C 1817) challenged Dr. Bhutani's conviction and sentence on various felony offenses arising under the Federal Food, Drug, and Cosmetic Act (the pharmaceutical fraud). Accordingly, Appellant should not be precluded from pursing this appeal on the basis that this matter arises from an unauthorized, successive Section 2255 Motion.

However, the District Court properly denied Dr. Bhutani's Motion for a Certificate of Appealability pursuant to 28 U.S.C. § 2253 (c), having expressly found that "defendant had not made a substantial showing of the denial of a constitutional right." A Certificate of

Appealability is a prerequisite to the bringing of this appeal. Accordingly, this appeal should be dismissed.

Respectfully submitted,

PATRICK J. FITZGERALD
United States Attorney

by: ______________________________
PATRICK S. LAYNG
Assistant U.S. Attorney
Northern District of Illinois
Everett M. Dirksen Federal Building
219 South Dearborne Street
Chicago, Illinois 60604
(312) 886-7633

LAWRENCE G. McDADE
Deputy Director
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 307-0138

CERTIFICATE OF SERVICE

The undersigned hereby certifies that true and accurate copies of the JURISDICTIONAL MEMORANDUM have been served upon counsel for Baldev Raj Bhutani, by sending, via First Class mail, copies of the foregoing to Mark L. Shaw, 33 North Country Street, Suite 302, Waukegan, IL 60085; and also served directly upon Baldev Raj Bhutani by sending, via First Class mail, copies of the foregoing to: Baldev Raj Bhutani, Inmate No. 05458-424, P.O. Box 1000, Federal Prison Camp, Duluth, MN 55814, all on January 31, 2003.

Patrick S. Layng
Assistant US. Attorney
Northern District of Illinois